UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BLUE CROSS AND BLUE SHIELD ASSOCIATION, IN ITS CAPACITY AS THE CARRIER FOR THE SERVICE BENEFIT PLAN, A/K/A THE "FEDERAL EMPLOYEE PROGRAM," A FEDERAL EMPLOYEE HEALTH BENEFITS ACT PLAN,"

Plaintiff,

v.

JAZZ PHARMACEUTICALS PLC, JAZZ PHARMACEUTICALS, INC., JAZZ PHARMACEUTICALS IRELAND LIMITED, HIKMA PHARMACEUTICALS PLC, ROXANE LABORATORIES, INC., HIKMA PHARMACEUTICALS USA INC., AND EUROHEALTH (USA), INC., AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC., LUPIN LTD., LUPIN PHARMACEUTICALS INC., AND LUPIN INC.,

Defendants.

Case No. 1:20-cv-03543

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. This civil antitrust action for damages and injunctive relief alleges Jazz Pharmaceuticals—the drug company that makes and sells the narcolepsy drug Xyrem (sodium oxybate) that has current sales in excess of $1.4 billion per year—executed an overall anticompetitive scheme to impair and delay generic competition in the market for sodium oxybate oral solution. The scheme culminated in a series of payoffs to Jazz's would-be generic competitors, including the first-filer generic Hikma, that constitute unlawful market allocation agreements and anticompetitive reverse payments under *FTC v. Actavis Inc.*, 570 U.S. 136 (2013).

2. The plaintiff is a national health plan. Blue Cross and Blue Shield Association sues in its capacity as the carrier of the Service Benefit Plan a/k/a the Federal Employee Program which covers roughly 5.3 million federal employees, retirees and their families out of the nearly 8 million people who receive their benefits through the Federal Employees Health Benefits Program.

3. The defendant brand companies are Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, and Jazz Pharmaceuticals Public Limited Company (collectively, "Jazz"). The defendant generic companies are Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward Pharmaceuticals Corp.), Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc (collectively, "Hikma"), which are all related companies, and Amneal Pharmaceuticals LLC ("Amneal"), Par Pharmaceuticals, Inc. ("Par"), and Lupin Ltd, Lupin Pharmaceuticals Inc., and Lupin, Inc. (collectively "Lupin").

4. For much of the latter half of the 18 years that Xyrem has been on the U.S. market, Jazz committed a series of anticompetitive acts designed to impair or delay generic entry in the market for sodium oxybate oral solution. These acts include acquiring and enforcing bogus

patents, prosecuting citizen petitions before the FDA that had no realistic likelihood of success, and abusing the REMS-related FDA approval conditions for Xyrem to frustrate efforts by would-be generic competitors to gain FDA approval for their own generic versions of the product. In recent years, Jazz crafted a series of unlawful market allocation agreements with its would-be generic competitors. Under an early 2017 agreement, Jazz persuaded Hikma (the first company to file for approval for generic Xyrem) to withdraw meritorious challenges to Jazz's patents and delay entry of Hikma's FDA-approved sodium oxybate generic until at least 2023, a period of about eight years. In exchange, Jazz promised Hikma that, when Hikma eventually did enter the market, Jazz would withhold competition from an "authorized generic" launched by Jazz. In agreements with other generics, Jazz carved the market through explicit limited supply distributorships, effectively ensuring the continued high prices for Xyrem through volume-limited supplies provided by Jazz to its would-be competitors. In exchange, these generics, too, dropped meritorious patent challenges and agreed to postpone generic entry for years.

5. Through Jazz's overarching anticompetitive scheme and by the unlawful payoffs to its would-be competitors, generic competition in the market for sodium oxybate oral solution was impaired and delayed, perhaps as long as until the end of 2025. Absent the unlawful conduct, unimpaired competition in that market would have begun as early as January 2018. Meanwhile, the plaintiff health plan and all other members of the proposed class have paid, and continue to pay, massive overcharges for Xyrem. On behalf of itself and all others similarly situated, the plaintiff seeks damages and injunctive relief.

II. PARTIES

6. The plaintiff Blue Cross and Blue Shield Association ("BCBSA") is a national association of 36 independent and locally operated Blue Cross and Blue Shield companies

providing health plans to over 107 million members nationwide. BCBSA's principal place of business is located at 225 North Michigan Ave., Chicago, IL 60601.

7. BCBSA brings this action in its capacity as the carrier of the Service Benefit Plan a/k/a the Federal Employee Program ("FEP"), one of the Federal Employee Health Benefits Plans ("FEHBP"). Beginning in 1960, the Office of Personnel Management ("OPM") contracted with BCBSA under the Federal Employees Health Benefits Act ("FEHBA") to establish the government-wide FEHBP known as the Service Benefit Plan, also commonly known as the FEP. The FEP has the largest enrollment of any FEHBP. Pursuant to plan participation agreements between BCBSA and BCBS companies, BCBSA contracts with OPM for BCBS companies to underwrite and administer the FEP in their individual locales. However, BCBSA pays for drugs purchased by FEP enrollees through BCBSA's pharmacy benefits manager, including the drugs at issue in this case. As the carrier under the contract with OPM and under the plan participation agreements, BCBSA has the sole authority to make decisions to bring actions on behalf of the FEP.

8. During the class period, FEP purchased, and/or reimbursed for thousands of prescriptions of, Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in multiple of the jurisdictions set forth in counts 7 through 13 of this complaint and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged in this complaint.

9. The defendant Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Its U.S. headquarters is located at 3170 Porter

Drive, Palo Alto, CA 94304, with offices in Philadelphia, PA and Ewing, NJ. Jazz principally develops, manufactures and markets brand name drugs.

10. The defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland.

11. The defendant Jazz Pharmaceuticals Public Limited Company is an Ireland public limited biopharmaceutical company organized and existing under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Jazz Pharmaceuticals plc common stock is publicly traded in the United States on the NASDAQ stock exchange. Jazz Pharmaceuticals plc is the parent company of Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited.

12. Among other things, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited were parties to the document styled as the "Settlement Agreement" in this complaint. Among other things, Jazz Pharmaceuticals plc was directly involved in the negotiation of the unlawful agreements described in this complaint. Each of the three Jazz defendants was directly and substantially involved in planning and undertaking the anticompetitive acts alleged in this complaint.

13. The three Jazz entities are referred to collectively as "Jazz."

14. Jazz manufactures and sells Xyrem® (sodium oxybate) oral solution, the only product approved by the U.S. Food and Drug Administration (the "FDA") to be marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy.

15. The defendant Hikma Pharmaceuticals plc is a public limited company organized and existing under the laws of the United Kingdom, with its principal place of business at 1 New Burlington Place, London, W1S 2HR and its U.S. headquarters at 246 Industrial Way West, Eatontown, NJ, 07724.

16. The defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, NJ, 07724, and is a wholly-owned subsidiary of Hikma Pharmaceuticals plc. Before June 20, 2018, Hikma Pharmaceuticals USA Inc. was organized under the name West-Ward Pharmaceuticals Corp., which had been acquired by Hikma Pharmaceuticals plc in 1998.

17. The defendant Roxane Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43328. Roxane Laboratories, Inc. was purchased by West-Ward Pharmaceuticals Corp. in 2016 and is now a wholly-owned subsidiary of Hikma Pharmaceuticals plc.

18. The defendant Eurohealth (USA), Inc. is a holding company for Hikma Pharmaceuticals USA Inc. and a wholly-owned subsidiary of Hikma Pharmaceuticals plc, organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, NJ, 07724.

19. Among other things, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc were parties to the document styled as the "Settlement Agreement" in this complaint. Each of the Hikma-related defendants

was directly and substantially involved in planning, entering into, and performing under the agreements reached beginning in 2017, as alleged in this complaint.

20. The defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey, 08807.

21. The defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Ram Ridge Rd., Chestnut Ridge, NY 10977. Par is a subsidiary of Endo International plc, an Irish public limited company with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses relevant predecessors-and-successors-in-interest.

22. The defendant Lupin Ltd. is a public limited company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India.

23. The defendant Lupin Pharmaceuticals Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202.

24. The defendant Lupin Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202.

25. All of the defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

III. JURISDICTION AND VENUE

26. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the defendants. The Court further has jurisdiction over this action pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 as this action also alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. The Court also has jurisdiction over the claims under the various state laws under both 28 U.S.C. § 1332(d) and 28 U.S.C. § 1367(a).

27. This action seeks to recover treble damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiff and members of the class resulting from the Jazz defendants' monopolization and from all defendants' conspiracy to restrain trade in the United States market for Xyrem and its generic equivalents. The action also seeks permanent injunctive relief against the defendants to undo and prevent the unlawful conduct alleged here.

28. Venue is appropriate within this district as defendants transact business here, and under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. § 1391(b) (general venue provision). Further, the defendants and/or their agents may be found in this district.

29. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The regulatory structure for approval and substitution of generic drugs.

30. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[1] manufacturers that create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application ("NDA").[2] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[3]

31. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") patents that claim the drug or a method of using the drug, and that could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[4] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[5]

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[1] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq.).

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(a), (b).

[4] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[5] 21 U.S.C. § 355(b)(1), (c)(2).

32. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources nor authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments.

33. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[6] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

34. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[7]

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[6] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

[7] 21 U.S.C. § 355(j)(8)(B).

35. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

36. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[8] Generics are dispensed about 95% of the time when a generic form is available.[9]

2. Regulatory exclusivities for new drugs.

37. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provided for exclusivities (or exclusive marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

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[8] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf.

[9] *Id.* at 51.

38. One such exclusivity, New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[10]

39. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[11]

40. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[12]

3. Abbreviated New Drug Applications and paragraph IV certifications.

41. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a) That no patent for the brand has been filed with the FDA (a "paragraph I certification");

b) That the patent for the brand has expired (a "paragraph II certification");

[10] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[11] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[12] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

c) That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d) That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[13]

42. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[14] Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

4. The first filer's 180-day exclusivity period.

43. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

44. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer

[13] 21 U.S.C. § 355(j)(2)(A)(vii).

[14] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

("first-filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[15] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.[16]

45. The 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer because a brand manufacturer (such as Jazz) can launch an AG at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

46. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.[17]

47. A first-filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

5. Patents are subject to judicial and administrative scrutiny.

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[15] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[16] Or, until its first-filer exclusivity has been forfeited. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

[17] F.T.C. v. Actavis, Inc., 570 U.S. 136, 144 (2013) (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

48. A patent may be valid or invalid, infringed or not infringed, and enforceable or unenforceable. Simply owning a patent does not entitle the patent owner to exclude others. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the PTO, by court decision, or by jury verdict.

49. A patent holder at all times bears the burden of proving infringement. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

50. A patent is invalid or unenforceable when: (i) the disclosed invention is obvious in light of earlier prior art; (ii) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material or submits materially false information to the PTO during prosecution; and/or (iii) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

51. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

52. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman

patent litigation cases resolved on the merits between 1992 and 2002.[18] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[19]

6. REMS programs encourages drug manufacturers to work cooperatively to establish single, shared programs.

53. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[20] Section 505-1(a)(1) of the FDAAA authorizes the FDA to require sponsors of drug applications to submit a proposed REMS program if the agency determines that such is needed to ensure that a drug's benefits outweigh its safety risks. A REMS can include a medication guide, patient package inserts, a plan for communicating with health care providers about risks, and/or restrictions on the distribution of the drug (*e.g.*, by requiring practitioners, pharmacies, or healthcare settings to obtain special certifications before dispensing the drug). As examples, the FDA notes that if a drug carries a risk of serious infection, a REMS action might be to require patient education about the initial warning signs of infection prior to prescribing; if a drug is known to bear a risk of liver damage, a REMS might require liver function monitoring while the patient is taking the drug; for drugs that can cause a severe allergic reaction, a REMS might require that only a certified healthcare professional can administer the product; for drugs

[18] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[19] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

[20] Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. § 301 et seq.).

that can cause severe birth defects, a REMS could require a negative pregnancy test before each prescription can be dispensed.[21]

54. The FDA can require a REMS before a drug enters the market, based on known risks, or after a drug has been approved, based on new evidence of risk. In determining whether a REMS will be required for a particular drug, the FDA considers factors including (i) the size of the population likely to use the drug; (ii) the seriousness of the disease; (iii) the drug's expected benefit; (iv) the expected duration of treatment; (v) the seriousness of adverse effects; and (vi) the drug's novelty.

55. Generally, single, shared REMS systems—i.e., jointly administered REMS programs—which may include more than one sponsor, or multiple NDAs and other ANDAs, are required for innovator and generic manufacturers in order to reduce the burden to the healthcare system, including regulatory oversight, of having multiple REMS programs for drugs in the same class. Single, shared REMS systems allow for cost sharing among sponsors, provide for single portal access to materials and other documentary information about the program, and allow prescribers and pharmacies to complete certification and other administrative requirements just once, rather than multiple times for each manufacturer.

56. The FDA may waive the single, shared system REMS requirement and permit the generic company to use a "different, comparable" aspect of the ETASU—Elements To Assure Safe Use, which are designed to "provid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable," including requiring the drug's sponsor to monitor and evaluate the implementation of the ETASU, if the agency finds that (i) the burden of forming a

[21] Presentation by Elaine Lippmann, Office of Regulatory Policy, CDER, FDA, Risk Evaluation and Mitigation Strategies (REMS), https://www.fda.gov/media/105565/download.

single shared system outweighs the benefits of having one, or (ii) an aspect of the REMS is covered by a patent or is a trade secret and the generic applicant certifies that it sought a license for use of that aspect and was unable to obtain one.

57. According to guidance issued by the FDA, FDA policy "makes clear that while the FDA encourages companies to work together to form a single, shared system, the agency will consider a waiver at any time (either upon request of the applicant, or on the agency's own initiative)."[22] The FDA, however, cannot force such cooperation under the FD&C Act.

58. One policy issue Congress and the FDA faced when establishing the REMS system was the potential for abuse of the system by brand companies. Such abuse can be tempting given the economic realities. Competition from generics that are AB-rated to the brand usually decimate the brand drug company's profits from the product. Within the first year of availability, generics typically capture all but a small percentage of the brand's market share.

59. As the FDA has explained: "One of the primary ways that FDA facilitates a competitive marketplace is through the efficient approval of generic drugs, which are often lower cost than brand drugs. Unfortunately, the process established by Congress may not always function as intended. At times, certain 'gaming' tactics have been used by brand drug companies to delay generic competition."[23]

60. The FDA has recognized that one gaming tactic concerns shared REMS requirements. In 2017, then Commissioner of the FDA, Scott Gottlieb, outlined the problem:

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[22] Statement from FDA Commissioner Scott Gottlieb, M.D., on New Policies to Reduce the Ability of Brand Drug Makers to Use REMS Programs as a Way to Block Timely Generic Drug Entry, Helping Promote Competition and Access (May 31, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policies-reduce-ability-brand-drug-makers-use-rems.

[23] RLD Access Inquiries.

> Current law requires that branded and generic companies try to reach agreement on the implementation of a single, shared system REMS rather than maintaining separate REMS for the branded drug and its generic competitor. Any generic drug application referencing a branded drug with a REMS with ETASU must use a single, shared system REMS with the innovator, unless the FDA waives that requirement and permits the generic drug to use a separate, comparable REMS program. But we know that negotiations to reach agreement on shared system REMS can take extended periods of time. This can block the timely entry of a generic competitor. I believe branded firms sometimes use these negotiations strategically, as a way to slow generic competitors.[24]

7. Citizen Petitions.

61. Citizen petitions are a means by which any interested person can request that the FDA issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action.

62. All citizen petitions must specify the action requested and include a statement of the factual and legal grounds supporting the petition.

63. In practice, the citizen petition process is often abused through the filing of petitions by brand drug manufacturers requesting that the FDA deny (or make more difficult, expensive, and time-consuming) the approval process of their would-be generic competitors. The factual and legal bases for these requests often purport to concern the safety and efficacy of the generic drugs seeking approval, or their bioequivalence to the brand. These arguments are typically lengthy and raise complex scientific issues.

64. Even when the arguments raised in these citizen petitions are meritless or request something the FDA was already doing or planning to do—something that happens all too

[24] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Improve FDA Review of Shared Risk Evaluation and Mitigation Strategies to Improve Generic Drug Access* (Nov. 8, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-improve-fda-review-shared-risk-evaluation-and.

often—the FDA is legally required to nonetheless thoroughly analyze and respond to them, diverting resources and delaying generic approvals.

B. The competitive effects of AB-rated generic and authorized generic competition.

65. Generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price. Typically, generics are 50% to 80% (or more) less expensive than their brand counterparts when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially direct purchasers.

66. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. According to the IQVIA Institute—the leading provider of data in the healthcare sector—since 2013, for drugs where a

generic is available, consumers purchase the generic 97% of the time.[25] The Federal Trade Commission ("FTC") has found that on average, within a year of generic entry, prices had dropped 85%.[26] As a result, competition from generics is viewed by brand manufacturers as a serious threat to their bottom line.

67. Generic competition enables purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

68. Until a generic version of the brand drugs enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can, therefore, continue to profitably charge supracompetitive prices. Brand manufacturers are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means—to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

69. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[27] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the

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[25] IQVIA Institute, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* at 14 (2018), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[26] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

[27] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

70. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

71. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[28]

72. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near-term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

73. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months (this percentage erosion of

[28] See, e.g., Tracy Regan, Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & ECON. 311 (2000).

brand sales holds regardless of the number of generic entrants.).[29] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[30]

3. Authorized generics, like other generics, compete on price.

74. An "authorized generic" (sometimes shortened to "AG") is a product sold under the authority of the brand's approved NDA. An AG, then, is chemically identical to the brand drug but is sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor.

75. If the 180-day exclusivity period applies to a first-filer ANDA, the exclusivity exists only to bar the FDA from approving another ANDA during that time period. The exclusivity does not apply to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not bar the entry of authorized generics; the statutory scheme does not prevent a brand manufacturer from marketing and selling an AG at any time.

76. The FDA has found that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman Amendments" to encourage competition and, as a result, "lower prices in the

[29] FTC 2011 AG Study at 66-67.

[30] *See* FDA, *What Are Generic Drugs?*, https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last updated Aug. 24, 2017).

pharmaceutical market."[31] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period."[32] Such competition, and the resulting price decreases, work to benefit drug purchasers.

77. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One study noted that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[33]

78. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

79. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[34]

80. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[35] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit

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[31] FDA letter at 11-12.

[32] *Id.* at 12.

[33] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[34] Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 Health Affairs 790, 796 (2007).

[35] FTC 2011 AG Study at 139.

sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

81. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this. PhRMA recognizes it.[36] Generic companies recognize it.[37] Brand companies recognize it.[38]

C. Manipulation of the regulatory structure to impair competition.

82. The brand manufacturer of a pharmaceutical product that has no generic competition in the marketplace gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins in excess of 70% or more, while making hundreds of millions of

[36] Brand industry group PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

[37] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

[38] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004), https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

dollars in sales. The ability to make those kinds of profit margins is what economists call market power.

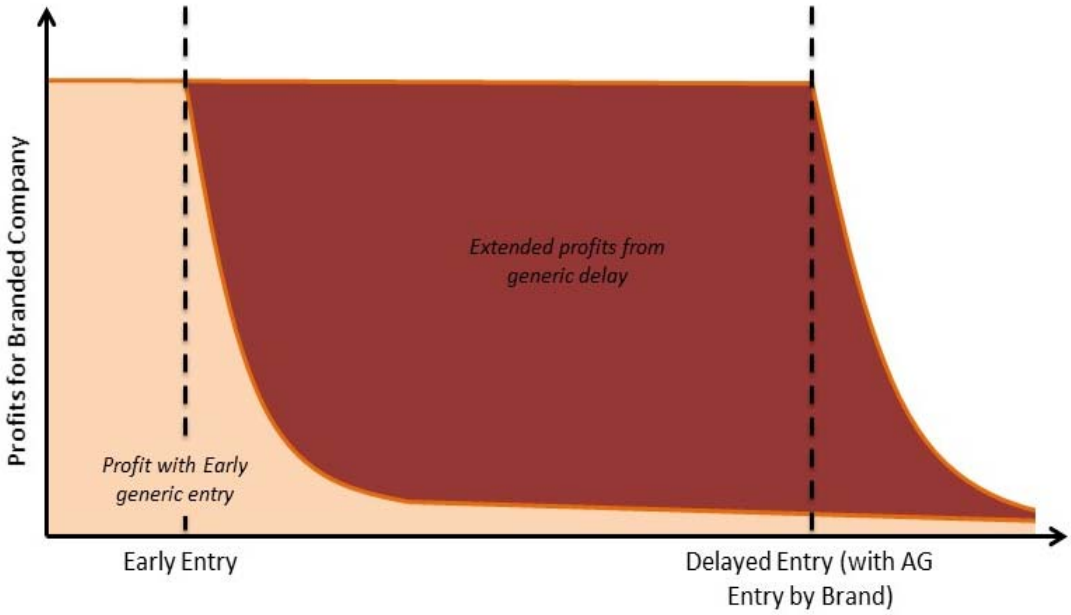
83. When a generic equivalent enters the market, however, it quickly captures 80% or more of the unit sales from the brand drug. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells almost all of the units, but at drastically reduced prices—delivering enormous savings to drug purchasers. And when multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

84. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from several generic manufactures—competition that severely depresses prices—from breaking out. If they work together to prevent or delay such competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. In other words, by stifling competition, the brand manufacture and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings that increased generic competition would have delivered to drug purchasers.

85. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the

latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (i.e., while the litigation is still pending) or prevails in the patent litigation and then launches its product.

Figure 1. Impact of Generic Delay on Brand Profits



86. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. After all, the generic manufacturer will not refrain from competing if it does not share in the profit gains through some means. The means usually takes the form of pay-offs from the brand manufacturer, deals are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

87. The brand manufacturer may choose to—unlawfully—pay off only the first-filer, even if other generic manufacturers are also lined up to challenge the patents. The first-filer's agreement to delay marketing its generic drug also prevents other generic manufacturers from marketing their products: none of the later filers can enter until the first-filer's 180-day exclusivity period has run.

88. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized. As a result, later-filing generics can be motivated away from competitively driven modest sales results and toward anticompetitive payoffs by brand companies. Under these unlawful arrangements, the brand shares some of its supracompetitive profits with the later-filing generics, and in exchange the later-filing generics to drop their patent challenges and accept a late agreed entry date.

89. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. They extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG agreements provide a means for brand and generic manufacturers to share the gains from conspiring.

90. In the 1990s, pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. Since the 2000s—as a result of regulatory scrutiny, congressional investigations, and class action lawsuits—brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide payoffs.

91. One form of payoff is a "no-authorized generic" or "no-AG" agreement. With a no-AG agreement, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market in exchange for the first generic agreeing to a delayed entry date.

92. Absent a no-AG promise, it often makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace. The AG entry affords the brand company a price strategy (competing with a low-priced generic), and this competition takes sales from what would otherwise be sold by the first-filer generic. Competition from an AG typically cuts the first filer's revenues about in half, and by having two generics in the market (the first-filer generic and the AG), the two generics compete on price. This lowers prices, delivering savings to drug purchasers.

93. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG during the exclusivity period. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by temporarily not competing with its AG. The brand manufacturer gains from the delayed onset of generic competition; the first-filer gains from the absence of generic competition for the first 180 days of marketing.

94. Drug purchasers lose. The brand and first-filer's reciprocal pledges not to compete harm purchasers thrice over. First, the pact delays the first-filer's generic entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. Second, by delaying the first-filer's entry, the pact also delays the time

when other, later, generics enter. Third, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first-filer's generic and the brand's AG.

95. For the first-filer generic, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[39]

Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.[40]

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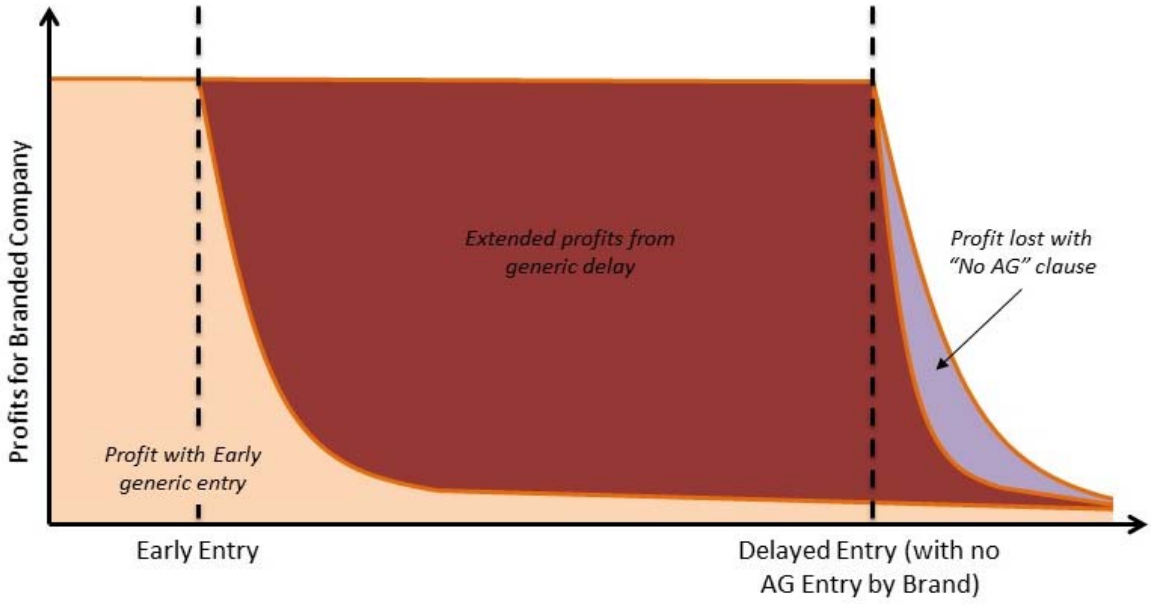
[39] "Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics," FTC (June 24, 2009), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf.

[40] *See In re Loestrin 24 Fe Antitrust Litig.*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25-26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

96. For a first ANDA filer (like Hikma) for a brand drug with more than a billion dollars in annual sales (like Xyrem), the difference between selling a generic without having to compete against another generic, whether AG or otherwise, amounts to tens, and in some instances, hundreds of million dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

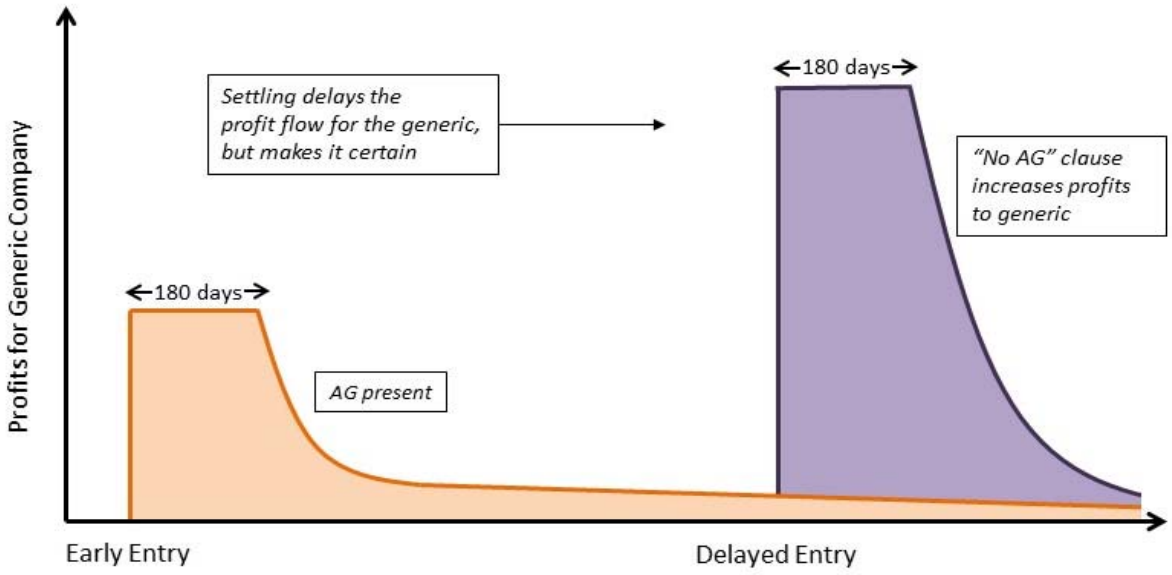
97. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

Figure 2. Impact of No-AG Clause on Brand Profits



98. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-AG agreement. Without a settlement, the generic could enter earlier—either when the 30-month stay expires ("at risk") or when it wins the litigation. The generic manufacturer's profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent, and (ii) it is expected that the brand manufacturer will launch an authorized generic and capture approximately 50% of the generic's sales. With a no-AG promise, the profit flow occurs later but is more certain and is larger—roughly twice the size—because the generic manufacturer does not lose half of the market to the brand manufacturer's authorized generic and can charge a higher price.

Figure 3. Impact of No-AG Promise on Generic's Profits



99. Pay-offs by means of no-AG clauses usually exceed the value that the first-filer generic could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-AG payoff, the first-filer converts that critical six months into a period of *total* generic exclusivity that it was not otherwise entitled to, thus doubling its unit sales and making those sales at a higher price.

2. Manufacturers also use anticompetitive "acceleration" clauses to delay competition.

100. Another tool in the pharmaceutical monopolist's belt are "acceleration" clauses, also referred to as "poison pills," which, when used in settling Hatch-Waxman litigation, dis-incentivize generic filers from entering the market by eliminating the possibility of any one generic obtaining *de facto* exclusivity (aside from the first-filing generic).

101. Brand manufacturers can induce generics to enter settlements by including these clauses in their agreements. In practice, such "acceleration" clauses do not accelerate generic entry—they delay it.

102. The purpose and effect of an "acceleration" clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market as quickly as they can. Absent the "acceleration" clause, other generic manufacturers would have an incentive to enter the market as soon as they were able, thereby enjoying a substantial period as the only ANDA-based generic product on the market. By eliminating this possibility, an "acceleration" clause results in delayed generic entry by, inter alia, disincentivizing generics that would otherwise be willing and able to come to market from doing so because of the knowledge that other generics would immediately flood the market.

103. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that "acceleration" clauses represent

"the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[41] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[42]

104. Scholars agree. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period appears to effectively deter other generics and, at least in the instances we observed, never to have resulted in an actual 'accelerated' entry." Indeed, the study found that in cases like this one where the first-filer retained its 180-day exclusivity, the use of "acceleration" clauses had not once promoted earlier generic entry. "Among the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first filer's entry was accelerated, and there were no

[41] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG- 110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

[42] Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which, as here, the first-filing generic retained the 180-day exclusivity.

cases in which a different generic entered before the entry date set in the first filer's settlement."[43]

V. FACTS

A. The development and approval of Xyrem.

105. In the late 1990s and into 2000, Orphan Medical Inc., of Minnetonka, Minnesota developed the use of sodium oxybate as a central nervous system depressant providing anti-cataplectic activity in patients with narcolepsy.

106. In September 2000, Orphan Medical submitted a new drug application seeking FDA approval to market sodium oxybate oral solution, 500 mg/ml in the United States to treat cataplexy associated with narcolepsy. The product was brand named Xyrem.

107. In July 2002, the FDA approved Xyrem (sodium oxybate oral solution) for the treatment of cataplexy (i.e., a sudden and transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, or terror) in patients with narcolepsy. (Later in 2005, the FDA also approved Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy).

108. Sodium oxybate is the sodium salt of gamma-hydroxybutyrate, commonly known as GHB, the active ingredient in Xyrem. GHB is a chemical that has been abused (misused). Abuse can cause serious medical problems, including trouble breathing, seizures (convulsions), loss of consciousness, coma, and death. Abuse of Xyrem could also lead to dependence, craving for the medicine, and severe withdrawal symptoms.

[43] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, Journal of Competition Law & Economics, 00(00), 1–32 at 1, 7.

109. At the time of the development of Xyrem, abuse of GHB was also designated by the Drug Enforcement Agency as a "date-rape drug." GHB is designated by the DEA as a Schedule I controlled substance under the Controlled Substances Act. Xyrem itself is a Schedule III drug under the CSA, i.e., it has a medium potential for abuse and abuse can cause severe mental addiction, or moderate physical addiction.

110. Xyrem is an oral solution that is recommended to be taken two times each night, the first dose right at bedtime and the second dose two-and-a-half to four hours later.

111. The original FDA approval of Xyrem was conditioned on implementation of a risk management program (or, "RiskMAP"). Components of the original plan included (a) implementation of a restricted distribution program for Xyrem, (b) implementation of a program to educate physicians and patients about the risks and benefits of Xyrem, (c) filling of the initial prescription only after the prescriber and patient have received and read the educational materials, and (d) maintenance of a registry of all patients and a record of all prescribers. In addition, at the time of the original approval, Orphan Medical agreed with the FDA (i) that each of the bulk drug and drug product would be manufactured at a single site, (ii) that the drug product would be stored at a facility compliant with Schedule III regulations, where a consignment inventory will be maintained, (iii) that the inventory would be owned by Orphan Medical, Inc., (iv) that the facility would be managed by a central pharmacy which would maintain the consignment inventory, and (v) that other than in the single central pharmacy, Xyrem would not be stocked in retail pharmacy outlets.

112. Since the original approval and under requirements requested by Orphan Medical, Xyrem has been dispensed through a single central pharmacy directly to patients under the RiskMAP (and a later, similar program to be discussed).

113. Subsequent to approval, the FDA granted Xyrem a New Chemical Entity ("NCE") exclusivity of five years from the NDA approval date, expiring on July 17, 2007, and orphan drug exclusivity of seven years from the NDA approval date, expiring on July 17, 2009. These government grants of exclusivity assured the lack of competition by generic versions of Xyrem through mid-2009.

114. In June 2005, a small drug company, Jazz Pharmaceuticals, acquired Orphan Medical (and thereby all rights to Xyrem).

115. By 2007, Jazz reported net sales of $39 million for Xyrem, which made up about three-quarters of the company's net sales of all products for the year. Over the years, Xyrem has continued to be the major product for Jazz. In 2019, Jazz reported total revenue from Xyrem of about $1.6 billion, which again accounted for about three-quarters of the company's net product sales.

B. The patents ostensibly covering aspects of Xyrem or its use.

116. Over time, at first Orphan Medical and later Jazz, filed for and obtained about 21 patents ostensibly claiming aspects of Xyrem and its use.

117. Jazz's patents are grouped into three patent families: the '431 family, the '730 family, and the '302 family. Because the active pharmaceutical ingredient in Xyrem, gamma-hydroxybutyrate, has long been known, none of the patents in these families claim the active pharmaceutical compound.

1. The '431 family of patents claim processes for making Xyrem, formulations of Xyrem, and methods of using Xyrem.

118. The '431 family of patents all claim priority to U.S. Patent Application No. 09/470,570, which Orphan Medical filed on December 22, 1999. The patents in the '431 family

include the following patents that Jazz and/or Orphan Medical requested be listed in the Orange Book as covering Xyrem:

'431 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
6,780,889	June 11, 2002	Aug. 24, 2004	July 4, 2020
7,262,219	July 7, 2004	Aug. 28, 2007	July 4, 2020
7,851,506	July 13, 2007	Dec. 14, 2010	Dec. 22, 2019
8,263,650	Apr. 13, 2012	Sept. 11, 2012	Dec. 22, 2019
8,324,275	Apr. 13, 2012	Dec. 4, 2012	Dec. 22, 2019
8,859,619	Nov. 26, 2012	Oct. 14, 2014	Dec. 22, 2019
8,952,062	March 6, 2013	Feb. 10, 2015	Dec. 22, 2019
9,539,330	Nov. 9, 2015	Nov. 8, 2016	Dec. 22, 2019

The '431 family of patents includes Orange Book-listed patents that claim pharmaceutical formulations of sodium oxybate or other salts of GHB (the '889, '219, '650, '619, and '330 patents) and/or methods of treating sleep-related conditions with sodium oxybate or other salts of GHB (the '506, '650, '275, and '062 patents).

119. The patents in the '431 family also include two patents that claim specific processes for manufacturing Xyrem. As process patents, they are not listable in the Orange Book.

'431 PATENT FAMILY: PROCESS PATENTS NOT LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry
6,472,431	Dec. 22, 1999	Oct. 22, 2002	Dec. 22, 2019
8,461,203	July 13, 2011	June 11, 2013	Dec. 22, 2019

120. The patents in the '431 family were set to expire on December 22, 2019, with the exception of the '889 and '219 patents, which received patent term adjustments under 35 U.S.C. § 154(b). In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents, and that six-month exclusivity will expire on June 22, 2020 (for the '506,' 650, '275, '619, '062 and '330 patents) or January 4, 2021 (for the '889 and '219 patents). The process patents were not eligible to be listed in the Orange Book and were not entitled to pediatric exclusivity, and so have expired.

2. The '730 family of patents claim methods of tracking prescriptions of a sensitive drug through a computer database.

121. The '730 family of patents all claim priority to U.S. Patent Application No. 10/322,348, which Orphan Medical filed on December 17, 2002. The '730 family of patents are all entitled "Sensitive Drug Distribution System and Method."

122. The patents in the '730 family include the following patents that Jazz and/or Orphan Medical requested be listed in the Orange Book as covering Xyrem:[44]

'730 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
7,668,730	Dec. 17, 2002	Feb. 23, 2010	June 16, 2024
7,765,106	Nov. 2, 2004	July 27, 2010	June 16, 2024
7,765,107	Apr. 1, 2005	July 27, 2010	June 16, 2024
7,895,059	Feb. 11, 2010	Feb. 22, 2011	Dec. 17, 2022

[44] The '730 family also includes United States Patent No. 7,797,171, which issued on September 14, 2010. The '171 patent claims *methods of obtaining FDA approval* for a prescription drug that uses a controlled distribution method involving an exclusive central computer database. Jazz did not list the '171 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Xyrem.

'730 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
8,457,988	Aug. 27, 2012	June 4, 2013	Dec. 17, 2022
8,589,182	Aug. 27, 2012	Nov. 19, 2013	Dec. 17, 2022
8,732,963	Aug. 22, 2012	May 20, 2014	Dec. 17, 2022

The patents in the '730 family "relat[e] to a drug distribution system for tracking prescriptions of a 'sensitive drug,'" which is "one which can be abused, or has addiction properties or other properties that render the drug sensitive."[45]

123. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity was listed in the Orange Book as December 16, 2024 for the '730, '106 and '107 patents and as June 17, 2023 for the '059, '988, '182, and '963 patents.

3. The '302 family of patents claim methods of treating sleep disorders with sodium oxybate in patients who are also taking divalproex sodium.

124. The '302 family of patents all claim priority to United States Patent Application No. 13/837,714, which Jazz filed on March 15, 2013. The '302 family of patents are all entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters."

125. The patents in the '302 family include the following patents that Jazz requested be listed in the Orange Book as covering Xyrem:[46]

[45] Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, 895 F.3d 1347, 1350 (Fed. Cir. 2018).

[46] The '730 family also includes United States Patent No. 7,797,171, which issued on September 14, 2010. The '171 patent claims *methods of obtaining FDA approval* for a prescription drug that uses a controlled distribution method involving an exclusive central

'302 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
9,050,302	Mar. 15, 2013	June 9, 2015	Mar. 15, 2033
8,772,306	Apr. 29, 2013	July 8, 2014	Mar. 15, 2033
9,486,426	May 8, 2015	Nov. 8, 2016	Mar. 15, 2033
10,213,400	Jan. 12, 2018	Feb. 26, 2019	Mar. 15, 2033

The patents in the '302 family claim methods of treating sleeping disorders by decreasing the amount of sodium oxybate or other salt of GHB administered to the patient if the patient is also taking valproate or divalproex sodium, medications used to treat seizures.

126. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity is listed in the Orange Book as September 15, 2033 for the patents in the '302 family with the exception of the '400 patent, which did not issue and was not listed in the Orange Book until 2019 and is not currently listed in the Orange Book with pediatric exclusivity.

C. The Jazz lawsuits against Roxane/Hikma.

127. On July 8, 2010, Roxane submitted ANDA 202090, seeking FDA approval to market an AB-rated generic version of Xyrem in 500 mg/ml strength. Roxane was the first generic to file, making it potentially eligible for 180-day exclusivity when its ANDA got approved. Roxane's ANDA proposed use of its own pharmacy dispensing program to meet risk requirements.

computer database. Jazz did not list the '171 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Xyrem.

128. Roxane's ANDA included paragraph IV certifications to the five patents that, at that time, were listed in the Orange Book for Xyrem: the '889 patent, the '219 patent, the '730 patent, the '106 patent, and the '107 patent.

129. On October 14, 2010, Roxane notified Jazz of its original ANDA filing and provided a detailed account of why the '889, '219, '730, '106 and '107 patents were invalid, unenforceable, and/or not infringed by Roxane ANDA product ("paragraph IV notice letter"). On November 22, 2010, Jazz filed suit against Roxane alleging infringement of these patents.

130. Over time, and as Jazz obtained additional patents and listed them in the Orange Book, Roxane would, in turn, send additional paragraph IV notice letters to Jazz, each certifying the new patent was invalid, unenforceable, and/or not infringed by Roxane's product. And Jazz responded by filing additional complaints alleging infringement. Those were:

COMPLAINTS FILED BY JAZZ AGAINST ROXANE

Complaint Date	Docket No. (D.N.J.)	Date Paragraph IV Notice Letter Received	Patent(s) in Suit
Nov. 22, 2010	2:10-cv-06108	Oct. 14, 2010	'889, '219, '730, '106,'107
Feb. 4, 2011	2:11-cv-00660	Jan. 10, 2011	'431, '506
May 2, 2011	2:11-cv-02523	Mar. 22, 2011	'059
Oct. 26, 2012	2:12-cv-06761	Oct. 5, 2012	'650
Dec. 5, 2012	2:12-cv-07459	unknown	'275
Feb. 20, 2015	2:15-cv-01360	Jan. 15, 2015	'203, '306, '619
June 1, 2015	2:15-cv-03684	Apr. 16, 2015	'062
Jan. 27, 2016	2:16-cv-00469	Dec. 14, 2015	'302
Aug. 12, 2016	2:16-cv-04971	Jan. 9, 2015	'963

131. By the time of the last complaint, Hikma (through its subsidiary, West-Ward Pharmaceuticals Corp.) had an agreement in principal to acquire Roxane. As a result, the last

complaint listed named as defendants not only Roxane but also Hikma Pharmaceuticals plc and Hikma subsidiaries West-Ward Pharmaceuticals Corp. and Eurohealth (USA), Inc.

132. In February of 2016, Hikma completed its acquisition of Roxane. Actions attributable to Roxane, Westward, and Hikma are, from this point forward, referred to just as "Hikma."

133. Over a period of about seven years—from the first lawsuit in 2010 through to an eventual settlement in 2017—the contentious litigation between Jazz and Roxane/Hikma included repeated acts by Jazz that unlawfully abused its patent positions. And often Jazz sought to enforce patents positions without any realistic likelihood of prevailing but knowing the prosecution would tie up the judicial processes to facilitate its overall goal of delaying or impairing generic entry.

134. During the litigation between Jazz and Hikma, Hikma asserted affirmative defenses based on Jazz's misuse of its patents. Specifically, Hikma argued that Jazz had engaged in "an abusive scheme to unfairly multiply [the patent] litigation" by:

> holding patent applications pending, gleaning [Hikma]'s noninfringement defenses from [Hikma]'s notice letters or from litigation, and then many years after issuance of the parent patents, filing continuation applications for new patent claims in an effort to forestall [Hikma]'s noninfringement defenses, more closely capture [Hikma]'s product, or delay the litigation. Then, upon obtaining its new patent claims, Jazz turns around and asserts those new patents in infringement claims against [Hikma]. Thus, the litigation never ends and [Hikma] is continually fighting a moving target.[47]

[47] Memorandum in Support of Roxane's Motion for Leave to Amend Its Answers, ECF No. 221, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:10-cv-06108 (D.N.J. May 3, 2013)

135. For example, in response to Jazz's original complaint alleging infringement of the '506 patent, Hikma asserted that it would not infringe the '506 patent because "all of the claims in the '506 patent required that the sodium oxybate solution be administered using a concentrated medium of 500 mg/ml of sodium oxybate," and the "administration of [Hikma]'s sodium oxybate solution required dilution of the concentrated medium prior to patient administration."[48]

136. Hikma disclosed this defense as part of the invalidity and non-infringement contentions it provided to Jazz in April and August 2011.[49]

137. Jazz then filed the patent applications that issued as the '650 patent and the '275 patent. Jazz filed these applications on April 12, 2012, 14 years after their parent application was filed.[50] These patents issued in September 2012 and December 2012, respectively. Both the '650 and '275 patents contain claims calling for dilution of the sodium oxybate solution prior to patient administration. Jazz then sued Hikma in October 2012 and December 2012, alleging infringement of the '650 and '275 patents.

138. Hikma contended that it did not infringe the '219 or '889 patents because the claims of those patents require the inclusion of "a pH adjusting agent" and Hikma's product did not contain a pH adjusting agent. Jazz then filed the application for the '650 patent, which included claims to compositions that do not require "a pH adjusting agent," and then asserted the '650 patent against Hikma after the patent issued.

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[48] Roxane Laboratories, Inc.'s Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint Regarding U.S. Patent No. 8,263,650, ECF No, 218-3, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:10-cv-06108 (D.N.J. Apr. 26, 2013), Affirmative Defenses ¶¶ 17-18.

[49] *Id.*, Affirmative Defenses ¶ 14.

[50] *Id.*, Affirmative Defenses ¶¶ 19, 27.

139. Hikma contended that it did not infringe the '431 patent because "[a]ll of the claims of the '431 patent require that sodium oxybate be 'added' to an aqueous medium" and "[Hikma] makes its sodium oxybate solution without 'adding' sodium oxybate to an aqueous medium." After learning of this defense, Jazz filed the patent application that issued as the '203 patent. Jazz filed this application on July 13, 2011. The claims of the '203 patent, which issued on June 11, 2013, include claims for "admixing" sodium oxybate with an aqueous medium rather than "adding" sodium oxybate to an aqueous medium, claims to a method that "contacts" a salt of GHB with an aqueous medium, and claims that do not specify how sodium oxybate is combined with the aqueous medium to prepare the composition. Jazz then asserted the '203 patent against Hikma after the patent issued.

140. In response, Hikma asserted that because "Jazz continues to seek and obtain new patents, add patents to the Orange Book, bring patent infringement suits against [Hikma], including to seek consolidation of all suits relating to [Hikma]'s sodium oxybate ANDA product," Hikma had suffered and would "continue to suffer material prejudice by being forced to indefinitely defend itself against patents that were not invented by the named inventors but are based on information gleaned by patent attorneys during a litigation, causing [Hikma] to face an 'at-risk' launch of its sodium oxybate product due to delayed resolution of this litigation."

141. It was still early in Jazz's scheme that culminated in the reverse payment agreements, but with Hikma already discussing launch "at risk" of Jazz's patent thicket, Jazz knew it needed to fortify its barriers.

D. The Jazz "single pharmacy" REMS program for Xyrem

142. In 2007, Congress passed the Food and Drug Administration Amendments Act (the "FDAAA") that set forth a comprehensive statutory framework for a Risk Evaluation and Mitigation Strategies ("REMS") program that, for particular drug products, requires a careful

balance between, on the one hand, the need to evaluate and mitigate risk of a drug to ensure that its benefits outweigh its risks, and, on the other, the potential burdens of REMS elements on patient access and the health care delivery system. The FDA then formalized the REMS regulatory program for the monitoring of medications with a high potential for serious adverse effect. A REMS program applies only to specific prescription drugs but can apply to brand name or generic drugs.

143. When creating the REMS program, Congress was particularly concerned that restrictions placed on access to a particular medication through a REMS program not become an artifice through which brand companies impaired the ability of companies to develop similar and generically equivalent drug products. Congress expressly prohibited the use of restrictions on use to "block or delay approval" of applications under sections 505(b)(2) and 505(j) of the FD&C Act.

144. Because at the time some products already had a form of a risk management program in place, there was a process by which the earlier approved risk program could be deemed a REMS program. For Xyrem, a risk management plan had been instituted as part of the original approval in February 2002, with a modified version of that plan being approved in November 2005. In March of 2008, the FDA deemed that plan to be a REMS program; however, Jazz was required to formally submit to the FDA a proposed REMS for review within 180 days of that notice.

145. In late August 2008, Jazz requested of the FDA that the existing risk management plan simply be approved as the new REMS approach for Xyrem under the FDAAA. That began a *seven-year* negotiation between Jazz and the FDA over the appropriate terms for the Xyrem REMS.

146. For example, when the FDA initially approved the RiskMAP in 2002 with the limitation that Xyrem be dispensed only from a single central pharmacy, the FDA had been led to believe that to be a good way to effectuate the overall restrictions on distribution necessary for safe use of the drug.

147. But in August 2009, as part of its transition from a risk management plan to a REMS, Jazz submitted a proposal to, among other things, remove the restriction to a single pharmacy and instead allow certification of multiple pharmacies. Its rationale for this proposed change was that it would "increase patient access without compromising patient safety." Jazz also stated that the single pharmacy program in existence at that time "imposes numerous impediments to patient access to Xyrem, possibly depriving narcolepsy patients of an important medication to control their EDS and cataplexy and potentially affect their lives dramatically."

148. By 2011—years into the discussion—Jazz had realized it could use the ongoing negotiations to delay generic entry. At that time, Jazz's 2002 RiskMAP was still under discussion with FDA to convert it to the REMS program. Xyrem was still not included on FDA's list of current REMS. And an industry commentator states that "[a]t this point, it's hard to say which will happen first: Jazz fixing its RiskMAP/REMS, or the generic appearing on the market."

149. In February 2014, Jazz completed the flip-flop, filing a formal dispute resolution request, appealing an FDA notification and claiming that the agency's "assertion that the closed-loop distribution system for Xyrem is no longer necessary is not only unsupported, it puts patients and others at risk." Jazz also argued that the FDA "lacked statutory authority to modify a REMS 'deemed' to be in effect by operation of FDAAA, and alternatively, even if FDA did have such authority, it could only be exercised to add restrictions to a REMS, not to modify or remove

elements." But even at that time, the Jazz CEO acknowledged that the single pharmacy REMS was "a piece of Xyrem exclusivity." And at an August 2014 meeting to discuss the ongoing dispute, a Jazz representative acknowledged that it might be possible for a distribution system that involves two, and perhaps more, specialty pharmacies to effectively prevent the abuse, misuse, and diversion of sodium oxybate.

150. During the process, the FDA expressed two primary public health goals: (i) to have a REMS that assures safe use of the drug, and (ii) to ensure that the REMS does not stand in the way of generic approval. But eventually, the FDA folded to Jazz's litigiousness.

151. In eventually granting the single pharmacy approach for the REMS, the FDA wrote that "[i]n light of the significant drain on Agency resources posed by the dispute, and the fact that the outcome of Jazz's challenge to the Agency's legal authority to require a modification to a 'deemed REMS' had the potential to affect only a small number of drug products, the Agency decided to approve the REMS Jazz had proposed (i.e., with the single, central pharmacy limitation), and deny the dispute as moot." The FDA's disapproval of Jazz's anticompetitive acts was clear:

> FDA is mindful of the statutory requirement under the FD&C Act that [terms of use] be 'commensurate with the specific serious risk[s] listed in the labeling' of the drug, that [terms of use] 'not be unduly burdensome on patient access to the drug,' and 'to the extent practicable,' that [terms of use] be structured 'so as to minimize their burden on the health care delivery system.' We also note that it is part of FDA's statutory mandate to approve generic drugs that meet the standard for approval.
>
> Pursuant to these statutory provisions, FDA has sought to finalize and approve the REMS for Xyrem since 2008. In doing so, we have faced repeated, lengthy delays. The REMS you submitted on November 7, 2014, which we are now approving, contains a requirement that Xyrem be distributed only by a single pharmacy. Jazz's position that a single pharmacy is critical to the safe use of Xyrem has not been a consistent one. In 2009, Jazz submitted a supplemental NDA for a new indication for Xyrem for treatment of

> fibromyalgia in which it proposed to include multiple certified pharmacies.
>
> However, by early 2011, after FDA declined to approve the fibromyalgia indication, Jazz changed its position. By that time, Jazz had been granted several patents related to its single pharmacy distribution system. In its 2013 SEC filings, Jazz noted that it expected FDA modifications to the Xyrem REMS and stated that, 'depending on the extent to which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced.' This statement, in conjunction with Jazz's change in position regarding the necessity of the single pharmacy requirement, suggests Jazz's awareness that the Xyrem REMS could have the effect of blocking or delaying approval of generic versions of Xyrem. Such an outcome would reflect the use of REMS to block or delay generic competition in a manner inconsistent with section 505-1(f)(8). It would also place an unjustified burden on patient access and on the healthcare delivery system.
>
> FDA is approving the REMS Jazz submitted on November 7, 2014, closing a chapter on a REMS that has been pending for 7 years -- far longer than could have been reasonably anticipated when FDAAA was enacted. Our action approving the REMS submitted by Jazz should not be construed or understood as agreement with Jazz that limiting dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh the risks under section 505-1 of the FD&C Act. We continue to be concerned that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system. No other currently approved REMS requires a sponsor to limit dispensing to a single pharmacy.

152. The industry's Pink Sheet subsequently reported that "the FDA's tone of disapproval is bound to be cited in the context of any antitrust cases that ensue."

E. The Jazz 2012 citizen petitions to the FDA.

153. In addition to filing patent infringement lawsuits against Hikma seeking to block Hikma's launch in court and abusing the REMS system, Jazz filed citizen petitions with the FDA to slow down the ANDA review and approval process.

154. On May 18, 2012, Jazz submitted to FDA a baseless citizen petition, Docket No. FDA-2012-P-0499, asking FDA to (i) immediately publish whether generic Xyrem ANDAs were required to prove bioequivalence to the brand using *in vitro* testing, *in vivo* testing, or both; (ii) not accept, review, or approval any ANDAs until after this information had been published, and (iii) require *in vivo* bioequivalence testing, including both fed and fasting conditions, "and a demonstration of onset of drug action similar to Xyrem," for any proposed ANDA product that differs from the brand in manufacturing process, pH, excipients, impurities, degradants or contaminants.

155. Jazz attached forty-nine exhibits to its May 2012 citizen petition, including numerous scientific studies spanning many hundreds of pages and, at footnote 2, an implicit threat to sue if FDA's review and response was not sufficiently thorough: "it would . . . be arbitrary and capricious for FDA to deny [the requests] without a substantive response."

156. On July 10, 2012, before FDA had responded to Jazz's May 2012 citizen petition, Jazz submitted to FDA a second citizen petition concerning the requirements for submission of ANDAs referencing Xyrem, Docket No. FDA-2012-P-0733, and asked the FDA to rescind the acceptance of any previously-accepted ANDA (including the ANDA submitted by Hikma) that did not include a proposed risk management system when accepted for FDA review, arguing that such ANDAs would not contain the same labeling and conditions as Xyrem, as required by law.

157. The July 2012 citizen petition further requested that the FDA (i) not accept for review any ANDA referencing Xyrem that did not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same labeling and conditions of use as Xyrem; and (ii) determine that if any sponsor, including Hikma, submitted an ANDA referencing Xyrem that did not contain a proposed risk

management system at the time it was accepted for review, or later submits or resubmits an ANDA that contains an adequate proposed risk management system, then such ANDA should be subject to a renewed automatic 30-month stay of approval in the event Jazz timely opted to initiate patent litigation based on such notice.

158. On November 13, 2012, the FDA denied Jazz's May 18, 2012 citizen petition, dutifully outlining its bases in 20 pages of single-spaced text and eighty-six footnotes.

159. The FDA found that, contrary to Jazz's contention, it is not required to publish bioequivalence guidance prior to accepting ANDAs, nor is it required to reject ANDAs submitted prior to such publication.

160. In denying Jazz's May 2012 citizen petition, FDA noted that publication of bioequivalence guidance is intended to benefit ANDA applicants, whereas the only beneficiary of Jazz's baseless interpretation is brand manufacturers like Jazz, "who will benefit from a delay in generic competition in the marketplace."

161. On December 13, 2012, the FDA denied in its entirety Jazz's July 2012 citizen petition finding, as with Jazz's May 2012 citizen petition, that none of the requests had merit.

F. The Jazz lawsuits against at least eight other generic companies.

162. After the first-to-file ANDA by Roxane, at least eight other generic manufacturers submitted ANDAs for approval of AB-rated generic versions of Xyrem:

OTHER ANDA SUBMISSIONS

ANDA Applicant	ANDA No.	Date of Initial Paragraph IV Notice Letter to Jazz
Amneal Pharmaceuticals, LLC	203631	Dec. 10, 2012
Par Pharmaceutical, Inc.	205403	Nov. 20, 2013

OTHER ANDA SUBMISSIONS

ANDA Applicant	ANDA No.	Date of Initial Paragraph IV Notice Letter to Jazz
Ranbaxy Laboratories Limited and Ranbaxy Inc.	203351	June 3, 2014
Watson Laboratories, Inc.	204952	Oct. 29, 2014
Wockhardt Bio AG	207526	June 8, 2015
Lupin Ltd. and Lupin Pharmaceuticals Inc.	207415	July 23, 2015
Ascent Pharmaceuticals, Inc.	210523	June 14, 2017
Mallinckrodt plc, Mallinckrodt Inc., and Mallinckrodt LLC	210936	Nov. 21, 2017

163. After each ANDA applicant sent its initial paragraph IV notice letter to Jazz, Jazz filed patent infringement actions against each applicant. And as Jazz acquired more and more patents, Jazz brought additional suits against these other would-be Xyrem generic drugmakers.

164. Under the Hatch-Waxman Act, Jazz's filing of these lawsuits—irrespective of their prospects of success—triggered automatic 30-month stays, running from the date Jazz received the generic manufacturer's paragraph IV notice letter. These stays prevented the FDA from granting final approval of these ANDAs until the earlier of (i) the expiration of the thirty-month stay, or (ii) entry of a final judgment that the patents at issue were invalid, unenforceable, and/or not infringed.

G. The notorious Jazz price increases for Xyrem.

165. Jazz was a small, relatively unsuccessful biotech before it leveraged the company to buy the Xyrem franchise. When in 2005 Jazz first acquired Orphan Medical, a one-year supply of Xyrem would cost about $5,000 to $10,000. But after a series of shockingly large price

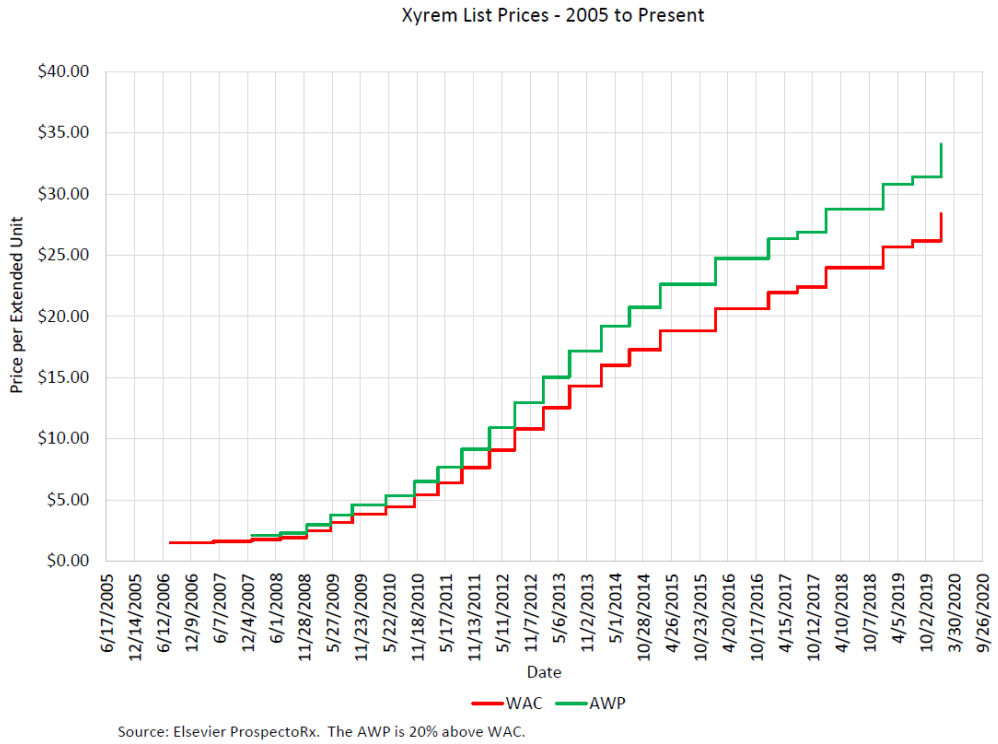
increases by Jazz for each of seven successive years, a one-year supply cost about $62,000 to $124,000.[51]

166. In 2014, Jazz came under heavy scrutiny for alleged pricing abuse on Xyrem. For example, in May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked *first* with an overall increase of 841% from 2007 to 2014. Bloomberg's data indicated the following percentage price increases:

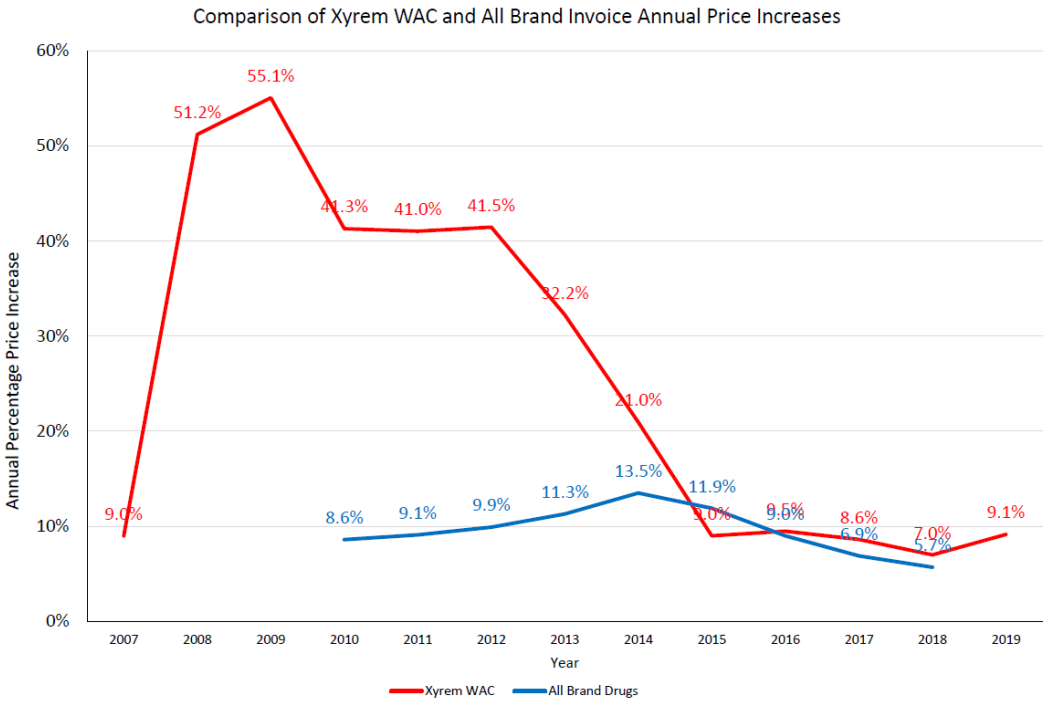
Year	Price Per mL	% Change from Previous Year
2007	$2.04	-
2008	$3.09	51%
2009	$4.60	49%
2010	$6.50	41%
2011	$9.17	41%
2012	$12.97	41%
2013	$17.15	32%
2014	$19.20	12%

167. The following chart details Jazz's dramatic pricing increases by tracking the list prices for Xyrem over the life of Jazz's monopoly over the drug:

[51] The recommended dose of Xyrem ranges from 4.5 to 9 grams, which converts to a monthly dosage range of 270 to 540 mL. So, in 2007, the yearly cost of Xyrem ranged from $6,609.60 to $13,219.20. But by 2014, the yearly cost for the drug had ballooned to a range from $62,208 to $124,416.



168. The pricing history of Xyrem stands in stark contrast to that of other branded drugs. From 2009 to 2018, Xyrem's WAC price increased a staggering 525%, as compared to an average of just over 100% for all other brand drugs for which data is available:



Sources: ProspectoRx; IMS Institute for Healthcare Informatics, "Branded Medicine Price Increases and the Impact of Off-Invoice Discounts and Rebates," November 2015, p. 4; IQVIA Institute for Human Data Science, "The Golbal Use of Medicine in 2019 and Outlook to 2023," January 2019, p. 11.

H. The patents in the '730 family are found invalid.

169. Beginning in January 2015, would-be generics for Xyrem filed a series of petitions with the PTAB for inter partes review of the '730 family of patents relating to the distribution system for sensitive drugs. Claims in all of the '730 family of patents were challenged in the proceedings.

170. Collectively, and as consolidated, Par and Amneal challenged claims in the '730, '106, '107, '059, '988, '182, and '936 patents.

171. Each of the challenged patents derive from the same original application: U.S. Patent Application No. 10/322,348, filed December 17, 2002 by Orphan Medical, and each contains, as noted above, claims relating to a drug distribution system and method that utilizes a central pharmacy and database to track prescription.

172. On April 28, 2016, Jazz settled with Wockhardt (one of the generics that was pressing IPR review), resolving not only the IPR proceedings, but the patent infringement litigation Jazz had filed against Wockhardt. That settlement agreement, according to Jazz's public filings, granted Wockhardt a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier" depending on the occurrence of certain events (the import of which is discussed later). The specific terms of the settlement agreements are confidential. Jazz and Wockhardt then sought, and were granted, termination of the IPR proceedings as to Wockhardt.

173. Days later, on May 9, 2016, Jazz settled with Ranbaxy. Ranbaxy, too, was granted a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier" depending on the occurrence of "certain events" (again to be discussed later). That settlement also is confidential. With its settlement, Ranbaxy's IPRs and civil counterclaims in the Hatch-Waxman litigation pending against it were terminated.

174. From July 2016 to March 2017, with just Amneal and Par remaining as petitioners, the PTAB issued a series of six decisions finding that "by a preponderance of the evidence" all claims of the '730, '106, '107, '059, '182, '988 patents, and claims 24, 26, and 27 of the '963 patent, were unpatentable as obvious.

175. The board found that these claims, which related to Jazz's REMS program and described a centralized database containing patient, physician and prescription information, were obvious because Orphan Medical had disclosed the program long before it filed the first patent application, i.e., Orphan's disclosure at a publicly-held FDA Advisory Committee meeting on June 6, 2001 and such information was posted to the FDA's website.

176. Jazz appealed the ruling to the Federal Circuit. In July 2018 that court affirmed the PTAB invalidity rulings, eviscerating Jazz's REMS patent portfolio for Xyrem.

I. Hikma obtains final ANDA approval for generic Xyrem.

177. On January 17, 2017, with its infringement trial with Jazz just six months away, Hikma obtained final approval from FDA for its generic Xyrem ANDA.

178. In its approval of Hikma's ANDA, the FDA also issued a decision to waive the requirements for a single, shared system REMS for Xyrem, meaning that Hikma was no longer required under FDA regulations to seek a license to rely on Jazz's Xyrem REMS protocol. The decision referenced the ANDAs of Hikma, Ohm, and Amneal, among other applicants whose names were redacted, and provided that they or any other generic sodium oxybate oral solution manufacturer could also rely on Hikma's REMS program (and not be required to use Jazz's).

179. In issuing its decision, the FDA reiterated the ANDA filers' allegations that "Jazz ha[d] engaged in a strategy that 'entails serial attempts to impose unreasonable contractual terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the process."[52] This "strategy" of obstructive negotiation by Jazz of the single, shared program went on for more than three years. Ultimately, the FDA determined that "[i]n the absence of a waiver of the SSS [single, shared system] requirement, the ANDA [redacted] and Jazz's failure to agree to SSS terms is likely to further delay the approval of a generic version of sodium oxybate," and accordingly waived the single, shared requirement for Xyrem.[53]

[52] *See* FDA Memorandum, Decision to waive the requirement for a single, shared system REMS for sodium oxybate oral solution, January 17, 2017, at 11, https://www.fda.gov/media/102913/download.

[53] *Id*. at 12-13.

J. The Jazz-Hikma reverse payment agreement.

180. By the spring of 2017, Hikma had received final FDA approval for its generic product, and no statutory exclusivities stood in the way for its market entry. Hikma's challenge to Jazz's remaining Xyrem patents was set for trial only a few weeks away. Under its approved application, there was no legal obstruction to Hikma entering the U.S. market with its own approved product, its own pharmacy arrangements, and its own approved REMS program.

181. Such a full market entry by Hikma would likely spur the immediate launch of a second generic in the form of a launch of a *bona fide* Jazz authorized generic. And to this point, Jazz had already settled with at least five other generic Xyrem ANDA filers, each of which was granted a license to enter with their generic product on or after December 31, 2025, or earlier depending on the occurrence of "certain events." Given tentative approvals already granted to other generic companies, Hikma's entry into the market would likely be followed, six months later, by other generic entries, thereby fully "genericizing" the U.S. market for sodium oxybate oral solution.

182. However, in early April 2017 Jazz and Hikma entered into an unlawful reverse payment agreement under which generic entry in the market for sodium oxybate oral solution was delayed and impaired for years.

183. The April 2017 Jazz-Hikma agreement was, in part, memorialized in three documents, a "Settlement Agreement," a "License Agreement," and an "AG Agreement," each of which was executed at the same time and effective upon dismissal of the last of the infringement lawsuits between Jazz and Hikma. Although these documents evince some of the agreements between Jazz and Hikma, other tacit agreements were also reached between Jazz and Hikma at the time.

184. The document styled as a "Settlement Agreement" between Jazz and Hikma was partially disclosed in the public securities filings for Jazz. Jazz and Hikma agreed to conceal from the public the other two documents as well as the tacit agreements between them. All the written and tacit arrangements between Jazz and Hikma in April of 2017 were negotiated simultaneously, are interdependent, and are collectively referred to in this complaint as the "Jazz-Hikma agreement."

185. Under the Jazz-Hikma agreement, Jazz and Hikma agreed to settle all of the outstanding patent litigation between them over the Xyrem patents. But the settlement was not based on the merits of the underlying patent litigation; instead, it reflected anticompetitive agreements reached between them.

186. Under the agreement, Jazz promised to provide Hikma with a form of an authorized generic distributorship (the "Hikma AG") under which Hikma would have the right to sell an authorized generic version of Xyrem in the U.S. and its territories, districts, possessions and the Commonwealth of Puerto Rico for an initial term of six months commencing "on January 1, 2023, or earlier under certain circumstances."

187. Under the agreement, after six months, Hikma would have the right to extend the initial six-month term and continue to sell an authorized generic version of Xyrem for up to a total of five years, i.e., through January 1, 2028.

188. Under the agreement, and as Jazz reported, during the period of Hikma AG sales, Jazz would "receive a meaningful royalty . . . on net sales of the authorized generic version . . . with the royalty rate increasing [during the initial period] based on increased net sales of the authorized generic version of Xyrem" and that a "substantial increase in the royalty rate" would apply if Hikma's sales of the authorized generic extended beyond one year.

189. Under the agreement, in addition to the "royalty" payments, Hikma would pay Jazz for supply of the authorized generic version of Xyrem.

190. Under the agreement, the timing of the right to enter with an authorized generic on January 1, 2023 "or earlier under certain circumstances" ostensibly meant earlier events related to the market entry of other generic versions of Xyrem, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time.

191. Under the agreement, the Hikma AG product was required to be distributed through the FDA-approved Xyrem REMS, i.e., the REMS program approved for Jazz's branded Xyrem, While the FDA's approval of Hikma's ANDA included a waiver that permitted Hikma's ANDA product to use a separate REMS from the Xyrem REMS, under the agreement Jazz-Hikma agreement, Hikma could not do so with the Hikma AG.

192. Under the agreement, Hikma agreed to reimburse Jazz for a portion of the services costs associated with the operation of the Xyrem REMS and distribution of the authorized generic version of Xyrem.

193. Under the documents in the agreement, Jazz and Hikma stated their agreement "permits [Hikma] to develop and implement the separate REMS approved with its ANDA, and permits Jazz to challenge the FDA's waiver decision and the separate REMS approved in connection with [Hikma's] ANDA, and to raise any other safety issues pertaining to Xyrem."

194. Under the agreement, the parties agreed that Hikma eventually would be allowed to launch its FDA-approved ANDA product. In the agreement, Jazz granted Hikma a non-exclusive license under the Xyrem patents to make, have made, and market its generic sodium oxybate product under the Roxane ANDA in the U.S., Puerto Rico, districts and territories,

which license was to be effective as early as six months after Hikma had been selling the authorized generic. However, if Hikma elected to launch its own generic product, Hikma would no longer have the right to sell the Hikma authorized generic product. In a later earnings call, Jazz Chairman and CEO Bruce Cozadd acknowledged its Hikma AG rights would expire if Hikma chose to launch its ANDA product:

> Hikma has a license to launch its generic product as of July 1, 2023, but it will no longer have the right to sell an AG product through the Xyrem REMS if it elects to do so.

195. Finally, under the agreement, Jazz agreed to pay Hikma an undisclosed sum of money ostensibly in "recognition of the savings inuring to Jazz in terms of the avoidance of costs and expenditure of time and resources" prosecuting the litigation against Hikma.

196. The April 2017 Jazz-Hikma agreement has a series of anticompetitive provisions that, taken together against the realities of pharmaceutical regulation and industry economics, were designed to, have had, and continue to have, substantial anticompetitive consequences.

197. *First*, the Jazz-Hikma agreement was designed to, and has had, the effect of delaying the entry into the market of Hikma's first-to-file ANDA generic until at least July 2023. Absent the unlawful payments to Hikma, a reasonable company in the position of Hikma would likely have entered the market as early as January 2018. That entry was delayed until at least July 2023, i.e., the date that technically, under the agreement, Hikma could decide to stop selling the Hikma AG and instead launch the Hikma FDA-approved generic.

198. *Second,* the Jazz-Hikma agreement was designed to, and may well have, the effect of delaying the entry into the market of Hikma's first-to-file ANDA generic well past July 2023 and until the end of December 2025. While technically, under the agreement, Hikma may launch its FDA-approved generic by July 2023, doing so would (a) forfeit its Hikma AG rights, (b) void any incentives by which Jazz might withhold launch its own AG product (e.g., the Hikma AG

"royalties"), and (c) trigger the rights of some other would-be generics to enter the market. As a result, Hikma would only switch from the Hikma AG product to its own product in the event that the economics were better on the ANDA side, which was likely to occur only in the event of bona fide competition from other ANDA-approved generic products. In short, the economics behind the agreements were designed to, and may well have, the likely impact of delaying entry of Hikma's generic product until the end of 2025, i.e., when the agreed entry date arrives for all would-be makers. The Jazz-Hikma agreement was designed to, and does have, the effect of prolonging as long as feasible the period of duopoly supracompetitive prices for Xyrem and the Hikma AG product.

199. The consequence has been, and will be, that supracompetitive prices for Xyrem are unnecessarily charged for sodium oxybate oral solution while only NDA-approved versions of the product are on the market, and those supracompetitive prices will remain until full and fair generic competition. Hikma's agreement to delay entry was induced by the market allocation payments in the agreement.

200. *Third,* the Jazz-Hikma agreement was designed to, and does have, an explicit or *de facto* commitment on the part of Jazz not to launch its own authorized generic of Xyrem during at least the first six months that Hikma eventually on the market (the "Jazz no-AG commitment"). Among other things, (i) by providing that the first-to-file generic—Hikma—would be the company that would enter as an authorized generic, and (ii) by providing "meaningful" payments from Hikma back to Jazz during the time it was on the market with the Hikma AG, Jazz would have no incentive to also launch a *bona fide* AG of its own to challenge the Hikma AG sales. Instead, the agreement was designed to, and does have, the effect that during at least the first six months of entry (before subsequent generics were allocated a slice of

the market in their own separate pay-for-delay agreements, as discussed below), the Hikma AG would be the only authorized generic.

201. The consequence is that at least during the initial six-month period after the Hikma AG is eventually launched on January 1, 2023, the only two sodium oxybate oral solution products on the market will likely be Xyrem and the Hikma AG, with each then able to command highly supracompetitive prices for sodium oxybate oral solution. And because Hikma could not sell its own generic while it was selling the Hikma AG, the agreement ensured that there was only one generic—of any kind—on the market.

202. *Fourth*, the Jazz-Hikma agreement was designed to, and does have, the effect of significantly limiting both the extent to which Hikma AG sales would cut into Xyrem sales, and the extent to which Hikma AG sales would be discounted to Xyrem sales. Under the agreement, Hikma was required to use the Xyrem REMS for its Hikma AG product. As a result, all Hikma AG product will be required to be delivered by Jazz directly to the same, single central pharmacy used by Jazz for Xyrem—it appears that Hikma would never take delivery of any AG product, nor have the ability to introduce competition into the market by increasing the number of companies dispensing to patients.

203. *Fifth,* the Jazz-Hikma agreement was designed to, and has had, the effect of hindering other generic companies from coming into the marketplace. It does so by delaying the availability of a second REMS program, with additional dispensaries, for use by later generic entrants. The requirement in the agreement that Hikma use the Xyrem REMS for the Hikma AG product reduced the availability for other generics to gain market entry by use of the Hikma ANDA approved REMS, delaying later generic market entry.

204. *Sixth,* the Jazz-Hikma agreement was designed to, and has had the effect of, hindering later generic entry by providing a form of a most favored entry clause (sometimes given the dubious term "acceleration clause") that would provide disincentives to later generics to continue challenges to the Xyrem patents. By allowing Hikma to enter with the Hikma AG product on the "earlier events" of either "market entry of other generic versions of Xyrem" or "a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable," the most favored entry provisions reduced incentives for other generics to seek earlier generic entry.

205. *Seventh,* the fact that the Jazz-Hikma agreement effectuated delayed market entry by Hikma is shown by the entry term enabling earlier Hikma AG entry in the event of "a substantial reduction in Xyrem net sales over specified periods of time." Jazz did not have any arguable patent rights to exclude entry dependent on the extent of its Xyrem sales, nor did Hikma have any argument that it would not infringe a valid Xyrem patent claim based on the extent of Xyrem sales. Instead, the provision was added to the overall agreement because Hikma was delaying its market entry, and in return it needed a commitment that the size of that market would remain at specified levels; if not, it no longer needed to delay its entry.

206. *Finally,* the fact that the Jazz-Hikma agreement is anticompetitive by design and execution is shown by the terms that say the agreement "permits [Hikma] to develop and implement the separate REMS approved with its ANDA, and permits Jazz to challenge the FDA's waiver decision and the separate REMS approved in connection with [Hikma's] ANDA, and to raise any other safety issues pertaining to Xyrem." At the time of the settlement, Hikma *already had FDA approval* for its separate REMS program, a process that Jazz had fought tooth and nail. With the parties now settling outstanding issues yet preserving the ability of Jazz to

challenge the FDA's approval of the Hikma REMS program, the parties were now clearly on the same, anticompetitive side of seeking to limit the ability of other generics to gain market access.

207. The Jazz-Hikma agreement contains an unlawful reverse payment forbidden by the Supreme Court in *FTC v. Actavis*. The payment takes several forms.

208. *First*, the large payment to Hikma takes the form of the Jazz no-AG commitment, i.e., the promise by Jazz (either express, or implied by operation of the other terms of the settlement) not to launch its own AG product in competition with the Hikma AG. Unlike a typical, lawful patent settlement (where the parties agree to an entry date based on the relative merits of their legal positions), the Jazz-Hikma agreement includes a large and unlawful payment from Jazz to Hikma in exchange for Hikma's agreement to delay generic competition until later than the date Hikma would otherwise have been willing to accept. The absence of a *bona fide* AG on the market is not value that Hikma could not have gained in the litigation nor procured if it had launched its own, ANDA-approved product.

209. *Second*, the large payment to Hikma takes the form of *de facto* limitations on price competition that enable both Jazz and Hikma to make more money than they would under competitive conditions. The deal is structured to provide a "meaningful royalty" from Hikma to Jazz during the Hikma AG term, with the "royalty" rate increasing based on increased net sales of the Hikma AG. In effect, while Hikma sells some of the Hikma AG, the payback to Jazz is relatively small, but the payback increases when Hikma's net sales increase too much (making, of course, Hikma's ability to price against Jazz's product less likely). In effect, Hikma and Jazz allocate the market and keep prices high. This enables Hikma to earn far more through a collusive scheme than it would if it entered lawfully with its own ANDA-approved product.

210. *Third*, the provision that permits Hikma to use the Xyrem REMS program is also a large payment. By using the Xyrem REMS program rather than its own, FDA-approved Hikma REMS, Hikma can distribute product to patients without providing other generics a pathway to the market. Because Hikma has not operationalized its separate REMS program (agreeing instead to delay launching its ANDA product and sell an allocation of AG provided by the brand and sold under the brand's REMS program), subsequent generics faced yet another hurdle on their path to market: They would need to establish their own REMS program from the ground up before selling their generic versions of Xyrem. This is value that Hikma could not have gained in the litigation nor procured if it had launched its own, ANDA-approved product.

211. The combined reverse payments from Jazz to Hikma—in the forms of the no-AG commitment, the price support arrangement, and the use of the Xyrem REMS—is large under any view of the facts and within the meaning of *Actavis*.

212. Under the Jazz-Hikma agreement, Jazz is required to pay to Hikma a sum of money that approximates the avoided litigation costs of Jazz by settling the patent infringement litigations. As a result, *any* further payment of value from Jazz to Hikma is likely a large reverse payment, i.e., it will exceed avoided litigation costs.

213. Prior to discovery, precise quantification of the size of the large reverse payment that exists (beyond the avoided litigation costs) is difficult. However, several parameters apply.

214. The Xyrem market at the time of projected *bona fide* generic entry would have been about $1.5 billion per year. Under competitive conditions, a first-to-file generic company entering that market might expect about 40-45% market penetration, with the other 40-45% penetration going to a *bona fide* authorized generic. Facing competition from both the brand and two generics in the market, generic prices might likely fall 40-50%. So, during the first six

months, the first-to-file generic might likely estimate sales of about $150 million to $202.5 million.

215. Under the anticompetitive conditions created by the Jazz-Hikma agreement, Hikma stands to make markedly more. Putting aside functional limitations on quantity and price calibrated by undisclosed provisions of the agreement (addressed momentarily), under typical industry assumptions the Hikma AG will gain 80-90% of generic sales, and without other AG competition, will price the Hikma AG higher than it would under competitive conditions (e.g., 80% of the brand). The resultant sales to the Hikma AG under this parameter would be between $480 million to $540 million.

216. Under these parameters—shown simply to illustrate that a first-to-file generic can make huge sums more if it cuts an anticompetitive no-AG deal with the brand—Hikma would stand to make a very significant amount of money more if it did not share some of that money back with Jazz. (Under these parameters, in the vicinity of about $225 million to $360 million more).

217. In this case, the variable "royalties" in the Jazz-Hikma agreement are intended both (a) to kick back to Jazz some of that windfall to make up for the large amount Hikma gains by being the only generic on the market, and (b) to maintain a higher than usual level of pricing by Hikma.

218. In this case, there are unknown and complicating factors by both the varying "royalties" and the intended longevity of the lucrative Hikma AG that forestalls *bona fide* generic entry. But as a matter of sound applied microeconomics, in all events Hikma receives a payment markedly larger than it could review if it had entered the market under competitive conditions.

219. This calculation only accounts for the revenues to Hikma during the first year after launch. The agreement permits Hikma's AG sales to be extended for up to five years. It is fair to add to the parameters for measuring the size of the payment to Hikma that the size will increase due to the likely longer term of the Hikma AG.

220. On April 6, the day following the announcement of the Jazz-Hikma agreement, Jazz's stock rose sharply, from $140.65 at the close of markets on April 5, to $153.88 per share at the close on April 6, representing over 9% increase in value on septuple the normal trading volume. These price and volume changes are shown in the charts below:

221. This change represents an increase in Jazz's adjusted market capitalization of $785 million, as shown in the right-hand column of Table 1, below.

222. When analyzed using established methods of econometric modeling (reflected in Tables 1 and 2, below) the probability that the April 6, 2017 increase in Jazz's share price and trading volume occurred by chance is approximately zero, as shown in the "p-value" columns, below. Rather, it was a reaction to the Jazz-Hikma agreement.

TABLE 1: STOCK PRICE MOVEMENTS AROUND THE JAZZ-HIKMA AGREEMENT

Date	Days From Event	Actual Return	Predicted Return	Abnormal Return	Standard p-value	SQ Test p-value	Adjusted Market Cap Change ($M)
4/3/2017	-3	-1.53%	-0.28%	-1.25%	0.56	0.39	-$87
4/4/2017	-2	0.21%	0.06%	0.15%	0.94	0.89	$13
4/5/2017	-1	-1.79%	-0.50%	-1.29%	0.55	0.37	-$111
4/6/2017	0	9.41%	0.27%	9.13%	0.00	0.01	$785
4/7/2017	1	-0.06%	-0.16%	0.09%	0.97	0.93	$8
4/10/2017	2	-0.59%	0.08%	-0.66%	0.75	0.62	-$57
4/11/2017	3	0.07%	-0.25%	0.31%	0.88	0.83	$27

TABLE 2: ABNORMAL VOLUME OF TRADING IN JAZZ SHARES AROUND THE JAZZ-HIKMA AGREEMENT

Date	Days From Settlement	Trading Volume	Abnormal Volume	t-Statistic	p-Value
3/30/2017	-5	-52%	-41%	-0.715	0.476
3/31/2017	-4	-19%	0	-0.218	0.828
4/3/2017	-3	-12%	-7%	-0.116	0.908
4/4/2017	-2	-50%	-39%	-0.690	0.492
4/5/2017	-1	6%	4%	0.070	0.944
4/6/2017	0	332%	343%	5.995	0.000
4/7/2017	1	2%	15%	0.266	0.791
4/10/2017	2	-29%	-10%	-0.178	0.859
4/11/2017	3	3%	15%	0.254	0.800
4/12/2017	4	-34%	-23%	-0.410	0.683
4/13/2017	5	-48%	-36%	-0.637	0.525

223. Stock prices reflect investors' expectations about a company's ability to continue generating cash flows and value for shareholders. Changes in the stock price reflect changes in these expectations.

224. The spike in Jazz's stock price implies that, prior to the settlement, the company's shareholders were expecting generic competition to occur on a date earlier than permitted under the terms of the Jazz-Hikma agreement. There was also no corresponding drop in the price of Hikma's stock price.

225. The magnitude of the increase in Jazz's stock cannot be explained by factors such as increased certainty or other business arrangements. Rather, the jump in Jazz's stock price suggests the settlement included a payment to extend the agreed upon entry date later than was otherwise expected to occur and is thus evidence of the anticompetitive effects of the settlement.

K. Jazz enters into unlawful reverse payment agreement with Par, Lupin, and Amneal.

226. By 2018, Jazz had effectively forestalled generic entry for sodium oxybate oral solution. But while Hikma (the first-to-file ANDA applicant) and several other generics had

abandoned their challenges to the Xyrem patents, other generic companies continued to press forward. And if any of these later challengers succeeded, the entire market for sodium oxybate would become genericized, and along with that, almost all of Jazz's Xyrem sales. But settling these remaining patent challenges in a lawful manner based on the merits (or lack thereof) of Jazz's patent position would likely mean having to concede to an agreed entry date markedly earlier than had been the case for others. Competitive conduct would result in earlier generic entry for sodium oxybate.

227. Over the course of 2018, then, Jazz worked a series of anticompetitive reverse payment settlements with the three remaining, serious challengers to the Xyrem patents.

228. In January 2018, Jazz and generic maker Par entered into an anticompetitive reverse payment agreement (the Jazz-Par agreement").

229. Under the agreement, Jazz granted Par a right to sell a limited volume of an authorized generic version of Xyrem (the "Par AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Par was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume during the calendar year preceding the entry date of the Par AG. In effect, Jazz simply agreed to pay to Par a share of the supracompetitive profits it was gaining through the anticompetitive conditions it had created.

230. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Par agreed to abandon its challenge to Jazz's patents and delay launch of its own, true generic until December 31, 2025.

231. At the time of entering into the Jazz-Par agreement, Par was aware of the arrangements between Jazz and Hikma. Although unlawful, Par's acceptance of the terms of the

Jazz-Par agreement only made sense if Par knew that the Jazz-Hikma agreement operated, as a practical matter, as a limitation on Hikma's sales as well.

232. By entering into the Jazz-Par agreement, Par was also agreeing to, and becoming a part of, the overall arrangements to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Par agreement also provided a so-called "acceleration clause," which facilitated the horizontal market share by assuring that no participant to the market share would be able to jump the line to early generic entry.

233. Because Par was agreeing to delay its market entry, the Jazz-Par agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

234. The reverse payment from Jazz to Par is objectively valued in at least the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

235. In June 2018, Jazz and generic maker Lupin entered into an anticompetitive reverse payment agreement (the "Jazz-Lupin agreement").

236. Under the agreement and as it had done with Par, Jazz granted Lupin a right to sell a limited volume of an authorized generic version of Xyrem (the "Lupin AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Lupin was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume. In effect, Jazz simply agreed to pay to Lupin a share of the supracompetitive profits Jazz was gaining through the anticompetitive conditions it had created.

237. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Lupin agreed to abandon its challenge to Jazz's patents and delay launch of its own, true generic until December 31, 2025.

238. At the time of entering into the Jazz-Lupin agreement, Lupin was aware of the arrangements between Jazz, Hikma, and Par. Although unlawful, Lupin's acceptance of the terms of the Jazz-Lupin agreement only made sense if Lupin knew that the Jazz-Hikma-Par agreements operated, as a practical matter, as limitations on the other AG sales.

239. By entering into the Jazz-Lupin agreement, Lupin was also agreeing to, and becoming a part of, the overall arrangements to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Lupin agreement also provided a so-called "acceleration clause," which facilitated the horizontal market share by assuring that no participant to the market share would be able to jump the line to early generic entry.

240. Because Lupin was agreeing to delay its market entry, the Jazz-Lupin agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

241. The reverse payment from Jazz to Lupin is objectively valued in the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

242. In October 2018, Jazz and generic maker Amneal entered into an anticompetitive reverse payment agreement (the "Jazz-Amneal agreement").

243. Under the agreement and as it had done with Par and Lupin, Jazz granted Amneal a right to sell a limited volume of an authorized generic version of Xyrem (the "Amneal AG")

for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Amneal was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume. In effect, Jazz simply agreed to pay to Amneal a share of the supracompetitive profits Jazz was gaining through the anticompetitive conditions it had created.

244. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Amneal agreed to abandon its challenge to Jazz's patents and delay launch of its own, true generic until December 31, 2025.

245. At the time of entering into the Jazz-Amneal agreement, Amenal was aware of the arrangements between Jazz, Hikma, Lupin, and Amneal. Although unlawful, Amneal's acceptance of the terms of the Jazz-Amneal agreement only made sense if Amneal knew that the Jazz-Hikma-Par-Lupin agreements operated, as a practical matter, as limitations on the other AG sales.

246. By entering into the Jazz-Amneal agreement, Amneal was also agreeing to, and becoming a part of, the overall arrangements to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Amneal agreement also provided a so-called "acceleration clause," which facilitated the horizontal market share by assuring that no participant to the market share would be able to jump the line to early generic entry.

247. Because Amneal was agreeing to delay its market entry, the Jazz-Amneal agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

248. The reverse payment from Jazz to Amenal is objectively valued in the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

249. Although the precise percentage of the brand Xyrem market allocated to Jazz's would-be generic competitors under each of the agreements with Par, Lupin, and Amneal are not publicly known, the value of these allocations can be estimated by observing that every 1 percent of brand sales allocated represents a value of approximately $13.5 million per year, assuming $1.5 billion annual brand sales in the year preceding their entry and a discount of 10% off of brand pricing ($1.5B x 0.01 x 0.90 = $13.5 million).

250. As with the Jazz-Hikma agreement, Jazz's agreements with Par, Lupin, and Amneal will not increase overall output, nor significantly reduce price, nor increase consumer choice; it will merely substitute Par, Lupin, and Amneal as the sellers of millions of dollars' worth of branded Xyrem for the sole purpose of paying them to delay market entry of less-expensive generic Xyrem, preserving Jazz's massive monopoly profits in exchange for doling out a small slice of them to Par, Lupin, and Amneal. Individually and collectively, these agreements are classic market allocation. Had any one of the generic defendants with output capacity defected from the conspiracy and refused to restrict output, Xyrem and its generic equivalents would be available to the plaintiff and the class at lower prices, sooner.

251. Jazz has admitted that its series of reverse payment settlements with Hikma, Amneal, Lupin, and Par were designed to effectively allocate the Xyrem market.

252. In December 2019, the Jazz CEO noted that the settlements were structured in a way to specifically prevent full genericization and, therefore, any real pricing competition:

> So again, in the period starting in '23, and I would say, really '23 through '26, we're expecting authorized generic competition other

> than Hikma, the first to file, the other couple folks with *authorized generics have very limited volumes. So in terms of dynamics on price, it's – this is not what you would think of as a generic free for all*. So I'd point that out from '23 to '26. In terms of what payers will do [with respect to Jazz's product hop], I think, if payers see a therapeutic equivalent, equal safety and efficacy, I have a pretty good idea, they're going to pick the cheapest product. But the question is, particularly, if there isn't a huge price differential, whether they will force patients onto a less healthy product. And I think that's a little different from the dynamics you usually see, including some of the ones you've referenced.

253. Similarly, during a healthcare conference call on November 14, 2018, a senior official described the agreements and their ends as follows:

> And now I want to sort of lay out for you where we are with the generic landscape for Xyrem. Now our first filer, Hikma, settled with the agreement for them to launch an authorized generic on the 1st of January 2023. And what was said about that authorized generic, that authorized generic would provide Jazz with meaningful royalties and would provide Hikma with meaningful economics during that first year. And that authorized generic can last for up to 5 years. Post that first year, the royalties become even more meaningful for Jazz.
>
> Then 6 months later, after that 6-month exclusivity period for the first filer, 3 of the second filers get to come again with a limited generic. And they are limited to low single-digit volume of the previous year Xyrem sales. So again, relatively low incursion on Xyrem here. And they get to have that for up until the end of 2025 when all 8 of the second filers have the opportunity to bring a generic product forth.

254. With the vast majority of Jazz's revenue on the line, it becomes clear why Jazz decided to maximize the delay of true generic competition and its accompanying revenue cliff by entering into its series of reverse payment agreements. All of these settlements shared a common, unlawful element; a payment from Jazz in the form of a limited volume of product made under the brand's NDA to be sold by the would-be generic competitor at supracompetitive prices as a *quid pro quo* for the generics' agreement to delay launch of their own, true ANDA generic

version of Xyrem. In every one of these settlements, the amount of the payment was large, unexplained, and far in excess of any reasonable estimate of the parties' saved litigation costs.

255. By structuring the deals in this manner, Jazz was able to achieve several anticompetitive ends. First, the generic was assured a fixed amount of sales at only a very modest discount off of the brand's price; the generic manufacturer will easily sell its full allotment at supracompetitive prices, as there is no incentive for price competition of the sort occurring under true generic competition, effectively conveying a sizeable payment to each settling generic. Second, this deal structure implicitly (if not explicitly) assured the generics that, prior to an actual generic launch, an AG would not be launched in competition; each would-be generic can sell its full (limited volume) allotment of AG with or without competition from an AG sold by Jazz, so Jazz would only be taking sales away from its own brand sales (unlike when an AG is launched in response to a true generic competitor). And third, by permitting the settling generics' limited allotments of NDA product to be sold under the brand's REMS program, Jazz effectively prevented the launch of any separate REMS program for use by ANDA generics, thereby increasing the burden and expense for subsequent generics to bring their competing products to market.

L. Jazz plans for a "product hop" from Xyrem to a successor brand as the final step to in its anticompetitive scheme.

256. Because the vast majority of Jazz's overall revenues come from Xyrem sales, in addition to its scheme to delay Xyrem's loss of exclusivity, Jazz has for years been keenly focused on developing or acquiring new products to extend its revenue streams beyond it. Chief among them is Jazz's plan to develop a line extension for Xyrem: A product with a renewed term of patent protection, approved pursuant to a separate NDA (so generics would have to go back to the drawing board), but using the same active ingredient and indicated to treat the same

conditions. The benefit of this strategy is that, instead of developing or acquiring a product that treats a new condition or patient population, the brand manufacturer simply cannibalizes its own existing patient population from the legacy product (that is nearing the end of patent protection) to the successor product and then enjoys a new 20-year patent term.

257. This strategy is known in the industry as a "product hop," and it comes in two forms. First, a "soft switch," by which a brand manufacturer simply stops promoting the legacy version of the product and instead uses its vast promotional spending to shift patients and prescribers to the new version; or second, a "hard switch," which includes the additional step of discontinuing sales of the legacy product and, in extreme cases, seeking a determination from FDA that such discontinuance was for safety reasons. With any product hop, generics face an uphill battle to gain sales given their lack of promotional budget, but a hard switch that occurs prior to generic entry is a nail in their coffin. Given the pharmacy counter substitution mechanism by which generic sales are made, there are simply none to be had once prescriptions for the legacy brand are no longer being written. And if FDA makes a determination that sale of a brand product has been discontinued for safety reasons, no generics may be approved or sold.

258. In early 2017, Jazz was progressing on its hop strategy. It had multiple line extension prospects in development and one, a low-sodium reformulation of Xyrem code-named JZP-258, had shown promising early results and was preparing to enter phase III clinical trials. But there was one huge problem: Xyrem's first generic applicant, Hikma, had just overcome the last of Jazz's hurdles and, on January 17, 2017, obtained final approval of its ANDA and separate REMS program. Jazz knew that Hikma could launch its generic "at risk" at any time. And even if Hikma opted not to launch at risk of its patents, there was a May 2017 patent trial, which brought with it the very real likelihood that Jazz's Xyrem patent portfolio would be

tanked, opening the floodgates not just for Hikma, but for all generic Xyrem competition, years before Jazz's successor product would be ready for market. Jazz knew it had to act fast to prevent that; its very life as a company depended on it.

259. So, as detailed above, in April 2017, on the eve of trial, Jazz and Hikma finalized a settlement that included a payoff to induce Hikma to shelf its approved generic version of Xyrem. Jazz stock jumped as investors realized the unexpected windfall. Not long thereafter, Jazz's executives ramped up public discussion about their promising hop strategy.

260. On an August 8, 2017 earnings call, Jazz's CEO reported that the NDA for Xyrem's low-sodium successor product would be ready for filing as early as 2019. When asked whether the settlement with Hikma had any "guarantees in place on how much share they can have out of that low-sodium version as well" (apparently meaning in addition to the agreed market allocation on legacy Xyrem), Mr. Cozadd replied that, other than a "fairly typical" market decline provision, "[u]nder that settlement, Hikma does not have any particular participation in or -- well, our low-sodium programs, of which there are several, remain completely ours."

261. When asked later on the same earnings call whether Jazz planned to "effectuate a hard switch and stop supplying Xyrem to the market," following launch of its low-sodium product, Jazz's CEO did not rule out the strategy, but advised it was "too early to start commenting on commercial strategy."

262. On a May 8, 2018 earning call, Mr. Cozadd was asked, "how you think JZP-258 will be received in the market when Xyrem generics are available," particularly among those patients "without ongoing sodium-sensitive comorbidities." Mr. Cozadd reminded that, "under our current time lines, our hope is the 258 would be available before generics were available,"

and implied he did not foresee patients migrating back to the legacy generic once the hop to the low sodium product had been effectuated.

263. As of the filing of this complaint, it appears Jazz is on track to effectuate its planned product hop. Jazz's NDA seeking approval of JZP-258 was submitted to FDA on January 21, 2020. On March 25, 2020, Jazz announced the FDA had accepted its NDA for priority review with a "goal date" for FDA decision in July 21, 2020. Even if the FDA requires multiple review rounds prior to final approval, this still gives Jazz plenty of runway to effectuate its all-important hop strategy (whether "soft" or "hard") prior to generic Xyrem entry, exactly according to its anticompetitive plan.

M. Since its launch in 2002, Xyrem has been dispensed through a single specialty pharmacy operated by Express Scripts, to which title passes only momentarily.

264. Since its launch in October 2002, Xyrem has been dispensed directly to consumers through a single central pharmacy arrangement. The pharmacy appears to have at all times been Express Scripts Specialty Distribution Services, Inc. ("ESSDS")—a subsidiary of Express Scripts.

265. Under Jazz's and ESSDS's master services agreement, "all commercial, non-clinical trial [Xyrem] Product sold by Jazz Pharmaceuticals or made available through the PAP [Patient Assistance Program]" are dispensed through ESSDS, as further delineated in written work orders from Jazz. The service agreements require ESSDS to provide "pharmacy and REMS services" as the sole central pharmacy to administer the Xyrem REMS program. The Xyrem REMS program requires the dispenser to agree to "Ship XYREM directly to each patient or a patient-authorized adult designee, and track and verify receipt of each shipment of XYREM."

266. All commercial Xyrem sales are dispensed through ESSDS via its "Central Certified Pharmacy" i.e., the facility "licensed" in "compliance with the XYREM REMS

Program and utilized by ESSDS in connection with the performance" of the MSA. All non-PAP Xyrem orders must be furnished to the ESSDS Central Certified Pharmacy, where they are held for dispensation on a "consignment" basis.

267. The MSA provides that for some sales, title for the Xyrem product passes from Jazz to ESSDS only *momentarily* upon the point of "removal" from the ESSDS Central Certified Pharmacy. The transfer of title, however, applies only to products purchased as part of a "buy in" option (which has been redacted from the publicly filed settlement agreement), where "title transfers upon submission of a relevant purchase order." So, for just those defined applicable purchases, which are yet unknown, title is passed from Jazz to ESSDS only when in transit to the real purchaser—the consumer.

268. For these untold shipments, while ESSDS ostensibly has the "right to establish the price at which it resells" Xyrem, the MSA specifically provides that the price set by ESSDS "shall not exceed" the "greater of . . . [redacted in publicly filed settlement agreement] percent of [redacted in publicly filed settlement agreement] for" Xyrem. Under the MSA, the price at which ESSDS can sell Xyrem is adjusted by percentage of a particular benchmark price over a period of years. The particular percentages against the benchmark price, however, are redacted from the MSA.

269. In summary, (i) all Xyrem product sold by Jazz (and which will be sold as an authorized generic) are made by Jazz and pass through a single central pharmacy for direct delivery to patients, (ii) this arrangement has existed at all times, (iii) the same central pharmacy, ESSDS, has performed this service at all times, (iv) title remains with Jazz during the time that the central pharmacy holds the product, (v) the central pharmacy is paid by Jazz to perform the dispensing services (and Jazz will be reimbursed by the generic companies to the extent Jazz

makes such payments for the authorized generic sales), and (vi) the arrangements between Jazz and the central pharmacy limit the price at which Xyrem may be charged.

VI. MARKET POWER AND DEFINITION

270. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Xyrem, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases, his or her insurer) has the obligation to pay for the product.

271. Brand manufacturers, including Jazz, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

272. The relative unimportance of price to the prescriber reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced-price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Xyrem.

273. Through at least January 1, 2023, Jazz has had, and will continue have, monopoly power in the market for Xyrem. Jazz has had, and will continue to have, the power to exclude competition and/or raise or maintain the price of sodium oxybate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. When Hikma does come to market with an AG of Xyrem, Hikma and Jazz will have substantial market power in the market for Xyrem and its AB-rated generic equivalents because they will have the power to exclude competition and/or raise or maintain the price of sodium oxybate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

274. Before January 1, 2023, a small but significant, non-transitory increase to the price of brand Xyrem would not have caused a significant loss of sales. From January 1, 2023 forward until at least December 31, 2025, a small but significant, non-transitory increase in the price of generic Xyrem would not have caused a significant loss of sales.

275. Brand Xyrem does not exhibit significant, positive cross-elasticity of demand with respect to price with any other sodium oxybate product or treatment for narcolepsy other than AB-rated generic versions of Xyrem.

276. Brand Xyrem is differentiated from all other sodium oxybate products, and all other narcolepsy treatments, other than the AB-rated generic versions of Xyrem.

277. Jazz needs to control only brand Xyrem and its AB-rated generic equivalents, and no other products, in order to maintain the price of sodium oxybate profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would render defendants unable to profitably maintain their prices for Xyrem without losing substantial sales.

278. During the 180-day exclusion period starting in January 1, 2023, Jazz, with Hikma's conspiratorial aid, will sell brand Xyrem at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Jazz will enjoy high profit margins.

279. The defendants have, and have exercised, the power to exclude generic competition to brand Xyrem.

280. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected and continue to protect branded Xyrem from the forces of price competition.

281. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the defendants' ability to control the price of Xyrem, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (i) generic Xyrem would have entered the market at a much earlier date, at a substantial discount to brand Xyrem, but for the defendants' anticompetitive conduct; and (ii) Jazz's gross margin on Xyrem (including the costs of ongoing research/development and marketing) at all relevant times was very high.

282. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiff alleges that the relevant antitrust market is the market for Xyrem and its AB- rated generic equivalents.

283. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

284. Jazz's market share in the relevant market continues to be 100% until January 1, 2023, when Hikma enters the market at throttled capacity per its anticompetitive, reverse payment settlement agreement with Jazz.

VII. MARKET EFFECTS

285. The defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The defendants designed a scheme to delay competition on the products' merits to further Jazz's anticompetitive purpose of forestalling generic competition against Xyrem, in which Hikma cooperated in order to increase its own profits. The defendants carried out the scheme with the anticompetitive intent and effect of maintaining supracompetitive prices for sodium oxybate tablets.

286. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Xyrem from competition. These actions allowed Jazz to maintain a monopoly and exclude competition in the market for Xyrem and its AB-rated generic equivalents to the detriment of the plaintiff and all other members of the class, as defined below.

287. The defendants' exclusionary conduct delayed and continues to delay generic competition and unlawfully enabled Jazz to sell Xyrem without further generic competition. Were it not for defendants' illegal conduct, one or more additional generic versions of Xyrem would have entered the market sooner, and Hikma's generic product would face competition during its 180-day exclusivity period from a Jazz authorized generic product.

288. The defendants' illegal acts and conspiracy to delay generic competition for Xyrem caused the plaintiff and all members of the class to pay more than they would have paid for sodium oxybate absent this illegal conduct.

289. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant market, the plaintiff and members of the class would have paid less for sodium oxybate by: (i) paying lower prices on their remaining brand purchases of Xyrem, (ii) substituting purchases of less expensive generic Xyrem for their

purchases of more expensive brand Xyrem when market entry occurs (or should have occurred), and/or (iii) purchasing generic Xyrem at lower prices sooner.

290. Thus, the defendants' unlawful conduct deprived the plaintiff and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

291. During the relevant time period, the defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The defendants designed a scheme to delay competition on the products' merits, to further Jazz's anticompetitive purpose of forestalling generic competition against Xyrem, in which Hikma cooperated in order to increase its own profits. The defendants carried out the scheme, and continue to do so, with the anticompetitive intent and effect of maintaining supracompetitive prices for sodium oxybate.

292. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Xyrem, and later the generic defendants' sodium oxybate products, from competition. These actions allowed the defendants to maintain a monopoly and to exclude competition in the market for Xyrem and its AB-rated generic equivalents, to the detriment of the plaintiff and all other members of the class.

293. Were it not for the defendants' illegal conduct, generic Xyrem would have been available in the United States as early as January 2018, and certainly earlier than January 2023. In addition, were it not for the defendants' illegal conduct, when generic Xyrem did become available earlier, there would have been full and fair competition between the available generics, thereby reducing price to a competitive level.

294. The plaintiff BCBSA has incurred significant injury and damage as a result of the unlawful conduct of the defendants. During the period from January 2018 to the present, BCBSA

has paid and/or reimbursed for Xyrem at supracompetitive levels and has done so in at least the following states: Alaska, Arizona, California, Connecticut, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. If the conduct challenged in this complaint had not occurred, BCBSA would have paid for Xyrem under lawful competitive conditions, resulting in a substantial reduction in the amount it would have paid for Xyrem.

295. The plaintiff and members of the classes have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to payors such as the plaintiff and members of the classes.

296. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, the plaintiff and members of the classes would have paid less for sodium oxybate by (a) paying lower prices on their remaining brand purchases of Xyrem, (b) substituting purchases of less-expensive generic Xyrem for their purchases of more-expensive brand Xyrem, and/or (c) purchasing generic Xyrem at lower prices sooner.

297. The supracompetitive prices the plaintiff and members of the classes paid and continue to pay are traceable to, and the direct, proximate, and foreseeable result of the defendants' anticompetitive conduct.

IX. INTERSTATE AND INTRASTATE COMMERCE

298. During the relevant time period, Jazz manufactured, sold, and shipped Xyrem across state lines in an uninterrupted flow of interstate commerce.

299. During the relevant time period, the plaintiff and members of the classes purchased substantial amounts of Xyrem from Jazz and/or its agents. As a result of the defendants' illegal conduct, the plaintiff and the members of the classes were compelled to pay, and did pay, artificially inflated prices for Xyrem, and should have already been paying far less for a generic version of the drug were it available and but for the defendants' conduct.

300. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

301. The defendants' conduct was within the flow of and was intended to have and did have a substantial effect on, interstate commerce of the United States, including in this district.

302. During the class period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

303. The defendants' conduct also had substantial intrastate effects in that, among other things, distributors of Xyrem have been prevented from offering more affordable generic versions to purchases in each state. Defendants' conduct materially deprived the consuming public—including hundreds, if not thousands, of purchasers in each state—of any choice to purchase more affordable versions of Xyrem. The absence of competition to Xyrem has, and continues to, directly and substantially affect and disrupt commerce within each state.

X. CLASS ACTION ALLEGATIONS

304. For counts 1 through 6, 13, and 14, the plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure. The following is the proposed Federal Law Class:

> All individual persons or entities in the United States and its territories that purchased, paid for and/or provided reimbursement for some or all of the purchase price of Xyrem from Jazz or ESSDS, or any agents, predecessors, or successors of Jazz or ESSDS, during the time period from January 1, 2018 until the anticompetitive effects of the defendants' unlawful conduct cease (the "Class Period").

305. Excluded from the class are Jazz, Hikma, Amneal, Par, Lupin, Express Scripts and ESSDS, and any of their officers, directors, management, employees, parents, subsidiaries, and affiliates.

306. Also excluded from the class are fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members), any "flat co-pay" consumers who purchased Xyrem via fixed-dollar co-payment that does not vary based on the drug's status as a brand or generic, and pharmacy benefit managers.

307. Also excluded from the class are the government of the United States and all agencies thereof.

308. The class seeks damages for at least the four years preceding the date the complaint is filed, and permanent injunctive relief to prevent or remedy the unlawful conduct alleged herein.

309. For counts 7 through 12 and 13, the plaintiff bring this action on behalf of itself and all others similarly situated as a class action under Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure. The following is the proposed State Law Class:

> All individual persons or entities in the United States and its territories that, other than for resale, purchased, paid for and/or provided reimbursement for some or all of the purchase price for Xyrem during the time period from January 1, 2018 through and until the anticompetitive effects of the defendants' unlawful conduct cease for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

310. Excluded from this alternative class are Jazz, Hikma, Amneal, Par, Lupin, Express Scripts and ESSDS, or any other persons or entities that purchased Xyrem for purposes of resale from Jazz, and any of their officers, directors, management, employees, parents, subsidiaries, and affiliates.

311. Also excluded from the class are fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members), any "flat co-pay" consumers who purchased Xyrem via fixed-dollar co-payment that does not vary based on the drug's status as a brand or generic, and pharmacy benefit managers.

312. Also excluded from the class are the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof.

313. Members of the classes are so numerous and geographically dispersed that joinder of all members is impracticable. The plaintiff believes that members of each class are numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The classes are readily identifiable from information and records in the possession of defendants and third parties.

314. The plaintiff's claims are typical of the claims of the members of the classes. The plaintiff's claims arise out of the same course of anticompetitive conduct that gives rise to the claims of the other class members. The plaintiff and all members of the classes were damaged by

the same wrongful conduct of the defendants—they paid supracompetitive prices for Xyrem and were deprived of the benefits of earlier and more robust competition from less expensive generic Xyrem as a result of the defendants' unlawful conduct alleged herein.

315. The plaintiff will fairly and adequately protect and represent the interests of the classes. The interests of the plaintiff are aligned with, and not antagonistic to, those of the other members of the classes.

316. The plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

317. Questions of law and fact common to the members of the classes predominate over questions that may affect only individual class members, because defendants have acted on grounds generally applicable to the entirety of each class, thereby making overcharge damages with respect to each class as a whole appropriate. Such generally applicable conduct is inherent in defendants' wrongful conduct. Questions of law and fact common to the classes include, but are not limited to:

a) Whether the defendants unlawfully maintained and continue to maintain monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b) To the extent procompetitive justifications exist, whether there were less restrictive means of achieving them;

c) Whether direct proof of defendants' monopoly power is available and, if so, whether it is sufficient to prove defendants' monopoly power without the need to define the relevant market;

d) Whether the defendants' scheme, in whole or in part, has substantially affected intrastate and/or interstate commerce;

e) Whether the defendants' unlawful agreements, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiff and the members of the classes;

f) Whether defendants conspired to delay generic competition for Xyrem;

g) Whether, pursuant to the reverse payment agreements, Jazz's promise not to compete against Hikma's generic product constituted a large and unexplained payment;

h) Whether the defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Xyrem;

i) Determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic conduct caused; and

j) The quantum of overcharges paid by the classes in the aggregate.

318. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

319. The plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT 1– VIOLATION OF 15 U.S.C. § 2
(AGAINST JAZZ)

320. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

321. As described above, before January 2023, Jazz will maintain its monopoly power in the relevant market and, after that point, will share its, monopoly power with Hikma first, followed by Amneal, Lupin, and Par in an illegal monopoly.

322. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

323. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 2. Such injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct.

COUNT 2 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND HIKMA)

324. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

325. Jazz and Hikma violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

326. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 1. The plaintiff's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Hikma's conduct unlawful.

327. But for Hikma's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for the plaintiff and the class would be lower, sooner.

328. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

329. As a direct and proximate result of Jazz and Hikma's anticompetitive conduct, the plaintiff was harmed and continues to be harmed in the form of overcharges.

COUNT 3 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND AMNEAL)

330. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

331. Jazz and Amneal violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

332. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 1. The plaintiff's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Amneal'a conduct unlawful.

333. But for Amneal's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for the plaintiff and the class would be lower, sooner.

334. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct

purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

335. As a direct and proximate result of Jazz and Amneal's anticompetitive conduct, the plaintiff was harmed and continues to be harmed in the form of overcharges.

COUNT 4 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND LUPIN)

336. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

337. Jazz and Lupin violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

338. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 1. The plaintiff's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Lupin's conduct unlawful.

339. But for Lupin's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for the plaintiff and the class would be lower, sooner.

340. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

341. As a direct and proximate result of Jazz and Lupin's anticompetitive conduct, the plaintiff was harmed and continues to be harmed in the form of overcharges.

COUNT 5 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND PAR)

342. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

343. Jazz and Par violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

344. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 1. The plaintiff's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Par's conduct unlawful.

345. But for Par's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for plaintiff and the class would be lower, sooner.

346. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

347. As a direct and proximate result of Jazz and Par's anticompetitive conduct, the plaintiff was harmed and continues to be harmed in the form of overcharges.

COUNT 6 – VIOLATION OF 15 U.S.C. § 1
(AGAINST ALL DEFENDANTS)

348. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

349. The defendants violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

350. The plaintiff has been injured in its business or property by the violation of 15 U.S.C. § 1. The plaintiff's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful.

351. From the launch of brand Xyrem in 2002 through present, Jazz possessed, and continues to possess, monopoly power in the relevant market—i.e., the market for sales of sodium oxybate in the United States. But for the defendants' wrongful conduct, as alleged herein, Jazz should have lost its monopoly power in the relevant market as early as January 1, 2018 and in any event well before 2023.

352. Starting in January 2023, Jazz will share its monopoly power. First with Hikma, and then, six months later, with Amneal, Par, and Lupin, as a result of its anticompetitive reverse payment and market allocation agreements with each. These agreements individually and collectively will cover a sufficiently substantial percentage of the relevant market to harm competition.

353. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct

purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

354. As a direct and proximate result of the defendants' anticompetitive conduct, the plaintiff was harmed and continues to be harmed in the form of overcharges.

COUNT 7 – MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW[54] (AGAINST JAZZ)

355. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

356. As described above, before January 2023, Jazz will maintain its monopoly power in the relevant market and, after that point, will share its monopoly power with Hikma first, followed by Amneal, Lupin, and Par, in an illegal monopoly.

357. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

358. Jazz knowingly and intentionally maintained and enhanced its monopoly power in the relevant market, as described herein, injuring the plaintiff and the class. Jazz accomplished this scheme by, inter alia,

[54] The plaintiff has delivered, or is contemporaneously delivering, notice of this action and copies of this complaint to the attorneys general in Arizona, Alaska, Connecticut, Hawaii, Minnesota, Missouri, Montana, Nevada, New York, Oregon, Rhode Island, South Carolina, and Utah. The plaintiff has also provided a notice of the pendency of this action and demand for relief to defendants pursuant to the laws multiple states, including Georgia and Massachusetts (claims under the laws of Georgia and Massachusetts will be added in this action should the defendants not meet BCBSA's demand), as well as Arizona, Maine, Montana, Nevada, New York, Oregon, Rhode Island, Utah, and West Virginia (which require notice concurrent with filing under their respective state consumer protection and/or antitrust laws).

a) Delaying generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra-competitive profits;

b) Keeping an authorized generic off the market during Hikma's 180-day generic exclusivity period, and, subsequently when Amneal, Lupin, and Par are permitted to enter with only limited quantities of generic Xyrem, through at least December 31, 2025, thereby allowing defendants to monopolize the generic market for Xyrem during the period, and allowing defendants to make supracompetitive profits;

c) Raising and maintaining the prices so that the plaintiff and other members of the class would pay supracompetitive prices for Xyrem; and

d) Otherwise conspiring to unlawfully monopolize the relevant market, including through the use of anticompetitive "acceleration" clauses.

359. The goal, purpose, and effect of Jazz's scheme was also to maintain and extend its monopoly power with respect to Xyrem. Jazz's illegal scheme allowed it to continue charging supracompetitive prices for Xyrem, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Jazz's scheme will allow Hikma to reap the benefits of reduced generic competition in the United States.

360. There is and was no legitimate, non-pretextual, procompetitive justification for Jazz's conduct that outweighs its harmful effects. Even if there were some conceivable justification, the conduct is and was broader than necessary to achieve such a purpose.

361. As a result of Jazz's illegal conduct, the plaintiff and members of the class were (and did), and continue to be (and do), compelled to pay more than they would have paid for Xyrem and/or its generic Xyrem absent defendants' illegal conduct. But for Jazz's illegal conduct, competitors would have begun selling generic Xyrem sooner, and prices paid for the drug or its generic equivalent, therefore, less.

362. Had manufacturers of generic Xyrem entered the market and lawfully competed with Jazz (and one another) in a timely fashion, the plaintiff and other members of the class

would have substituted lower-priced generic Xyrem for the higher-priced brand-name Xyrem for some or all of their Xyrem requirements, and/or would have paid lower net prices on their remaining Xyrem and generic Xyrem purchases.

363. But for Jazz's illegal conduct, competitors would have begun marketing generic versions of Xyrem well before January 2023, and they would be able to market such versions more successfully.

364. By engaging in the foregoing conduct, Jazz intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-27, et seq., with respect to purchases in Connecticut by class members.

d) D.C. Code §§ 28-4503, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class, and such conduct constitutes a predicate act under the Florida Deceptive Practices Act.

f) Haw. Rev. Stat. §§ 480-2, 480-9, et seq., with respect to purchases in Hawaii by members of the class.

g) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

h) Iowa Code § 553.5, et seq., with respect to purchases in Iowa by members of the class.

i) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

j) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the class.

k) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

n) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

o) Mo. Rev. Stat. §§ 407.020, et seq., with respect to purchase in Missouri by members of the class.

p) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by members of the class.

q) Neb. Rev. Stat. Ann. §§ 59-802, et seq., with respect to purchases in Nebraska by members of the class.

r) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

s) N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases in New Hampshire by members of the class.

t) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the class.

u) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

v) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the class.

w) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

x) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

y) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the class.

z) S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases in South Dakota by members of the class.

aa) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

bb) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

cc) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the class.

dd) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

ee) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

365. By engaging in the foregoing conduct, Jazz intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce

366. The plaintiff and members of the class have been injured in their business or property by reason of Jazz's violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz's conduct unlawful.

367. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 8 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND HIKMA)

368. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

369. During the Class Period, Jazz and Hikma engaged in a continuing contract, combination or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

370. During the Class Period, Jazz and Hikma entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

371. Jazz and Hikma's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

372. As a result of Jazz and Hikma's unlawful conduct, the plaintiff and other similarly situated purchasers in the class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

373. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Hikma did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

374. Jazz and Hikma's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Hikma delayed generic entry and its attendant lower prices for the plaintiff and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

375. Jazz and Hikma engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

376. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on the plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

377. By engaging the foregoing conduct, Jazz and Hikma intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut by members of the class.

d) D.C. Code §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Haw. Rev. Stat. §§ 480-2, 480-4, et seq., with respect to purchases in Hawaii by members of the class.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

g) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the class.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by consumer members of the class.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

l) Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

m) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the class.

o) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the class.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the class.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the class.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

v) R.I. Gen. Laws §§ 6-36-4 et seq., with respect to purchases in Rhode Island by members of the class.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the class.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

378. Jazz and Hikma intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by consumer members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

379. The plaintiff and members of the class have been injured in their business or property by reason of Jazz and Hikma's violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Hikma's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Hikma's conduct unlawful.

380. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 9 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND AMNEAL)

381. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

382. During the Class Period, Jazz and Amneal engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade

and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

383. During the Class Period, Jazz and Amneal entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

384. Jazz and Amneal's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

385. As a result of Jazz and Amneal's unlawful conduct, the plaintiff and other similarly situated purchasers in the class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

386. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Amneal did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

387. Jazz and Amneal's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Amneal delayed generic entry and its attendant lower prices for the plaintiff and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

388. Jazz and Amneal engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

389. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on the plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was

not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc*., 570 U.S. 136 (2013).

390. By engaging the foregoing conduct, Jazz and Amneal intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut by members of the class.

d) D.C. Code §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Haw. Rev. Stat. §§ 480-2, 480-4, et seq., with respect to purchases in Hawaii by members of the class.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

g) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the class.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by consumer members of the class.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

l) Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

m) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the class.

o) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the class.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the class.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the class.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

v) R.I. Gen. Laws §§ 6-36-4 et seq., with respect to purchases in Rhode Island by members of the class.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the class.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

391. Jazz and Amneal intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by consumer members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

392. The plaintiff and members of the class have been injured in their business or property by reason of Jazz and Amneal's violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Amneal's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Amneal's conduct unlawful.

393. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 10 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND LUPIN)

394. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

395. During the Class Period, Jazz and Lupin engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

396. During the Class Period, Jazz and Lupin entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

397. Jazz and Lupin's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

398. As a result of Jazz and Lupin's unlawful conduct, the plaintiff and other similarly situated purchasers in the class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

399. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Lupin did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

400. Jazz and Lupin's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Lupin delayed generic entry and its attendant lower prices

for the plaintiff and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

401. Jazz and Lupin engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

402. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on the plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

403. By engaging the foregoing conduct, Jazz and Lupin intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut by members of the class.

d) D.C. Code §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Haw. Rev. Stat. §§ 480-2, 480-4, et seq., with respect to purchases in Hawaii by members of the class.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

g) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the class.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by consumer members of the class.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

l) Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

m) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the class.

o) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the class.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the class.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the class.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

v) R.I. Gen. Laws §§ 6-36-4 et seq., with respect to purchases in Rhode Island by members of the class.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the class.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

404. Jazz and Lupin intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by consumer members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the class. Defendants engaged in unfair methods of

competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

405. The plaintiff and members of the class have been injured in their business or property by reason of Jazz and Lupin's violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Lupin's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Lupin's conduct unlawful.

406. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 11 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND PAR)

407. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

408. During the Class Period, Jazz and Par engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

409. During the Class Period, Jazz and Par entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

410. Jazz and Par's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

411. As a result of Jazz and Par's unlawful conduct, the plaintiff and other similarly situated purchasers in the class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

412. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Par did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

413. Jazz and Par's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Par delayed generic entry and its attendant lower prices for the plaintiff and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

414. Jazz and Par engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

415. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on the plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

416. By engaging the foregoing conduct, Jazz and Par intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut by members of the class.

d) D.C. Code §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Haw. Rev. Stat. §§ 480-2, 480-4, et seq., with respect to purchases in Hawaii by members of the class.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

g) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the class.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by consumer members of the class.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

l) Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

m) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the class.

o) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the class.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the class.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff

hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the class.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

v) R.I. Gen. Laws §§ 6-36-4 et seq., with respect to purchases in Rhode Island by members of the class.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the class.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

417. Jazz and Par intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by consumer members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

418. The plaintiff and members of the class have been injured in their business or property by reason of Jazz and Par's violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Par's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Par's conduct unlawful.

419. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 12 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST ALL DEFENDANTS)

420. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

421. During the Class Period, the defendants engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

422. During the Class Period, defendants entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

423. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

424. As a result of defendants' unlawful conduct, the plaintiff and other similarly situated purchasers in the class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

425. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, defendants did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

426. Defendants' conspiracy had the following effects, among others:

a) It delayed and continues to delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could and can monopolize the market and make supracompetitive profits;

b) It will keep an authorized generic from Jazz off the market during Hikma's 180-day generic exclusivity period, thereby allowing Hikma to monopolize the generic market for Xyrem during the period, and allowing Hikma to make supracompetitive profits;

c) It will, after Hikma's exclusivity period ends, continue to keep an authorized product from Jazz off the market as Amneal, Lupin, and Par enter with "very limited" quantities (throttled by Jazz) of generic Xyrem; and

d) It raised and maintained the prices that the plaintiff and other members of the class would and will pay for Xyrem at supracompetitive levels.

427. From January 2023 until at least December 31, 2025, Jazz will share its monopoly power with Hikma, Amneal, Lupin, and Par, and the companies will jointly maintain an illegal monopoly throughout that time.

428. The defendants engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

429. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on the plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc*., 570 U.S. 136 (2013).

430. By engaging the foregoing conduct, defendants intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the class.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California by members of the class.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut by members of the class.

d) D.C. Code §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the class.

e) Haw. Rev. Stat. §§ 480-2, 480-4, et seq., with respect to purchases in Hawaii by members of the class.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois by members of the class.

g) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the class.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the class.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by consumer members of the class.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland by members of the class.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the class.

l) Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota by members of the class.

m) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the class.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the class.

o) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the class.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the class.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the class.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York by members of the class, and to the extent New York law so requires, the plaintiff hereby forgoes any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the class.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the class.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the class.

v) R.I. Gen. Laws §§ 6-36-4 et seq., with respect to purchases in Rhode Island by members of the class.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the class.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the class.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the class, including citizens or residents of Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the class.

aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the class.

431. Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state consumer protection laws:

a) Alaska Stat. Ann. § 45.50.471, et seq., with respect to purchases in Alaska by members of the class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.

b) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above.

c) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the class.

d) Mo. Rev. Stat. §§ 407.020 et seq., with respect to purchase in Missouri by consumer members of the class.

e) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by consumer members of the class. Defendants engaged in unfair and deceptive acts and practices.

f) S.C. Code Ann. §§ 39-5-20, et seq., with respect to purchases in South Carolina by class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

g) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by consumer members of the class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

432. The plaintiff and members of the class have been injured in their business or property by reason of the defendants' violations of the laws set forth above, in that the plaintiff and class members were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for the defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes the defendants' conduct unlawful.

433. The plaintiff and class members accordingly seek damages and multiple damages as permitted by law.

COUNT 13 – UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

434. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

435. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

436. The defendants have reaped and retained substantially higher profits due to their unlawful scheme.

437. The plaintiff and class members have conferred and continue to confer an economic benefit upon the defendants in the form of profits resulting from the unlawful overcharges from Xyrem sales described herein, to the economic detriment of the plaintiff and members of the class.

438. The defendants' financial gain from their unlawful conduct is traceable to overpayments for Xyrem by the plaintiff and class members.

439. The plaintiff and members of the class have no adequate remedy at law.

440. It would be futile for the plaintiff and members of the class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Xyrem, as those intermediaries are not liable and would not compensate the plaintiff and class members for the defendants' unlawful conduct.

441. The defendants have benefited from their unlawful acts and it would be inequitable for defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by the plaintiff and the members of the Class for Xyrem sold by Jazz during the Class Period.

442. The financial benefits the defendants derived from overcharging the plaintiff and class members for Xyrem is a direct and proximate result of the defendants' unlawful practices described herein.

443. The financial benefits the defendants derived are ill-gotten gains that rightfully belong to the plaintiff and members of the class, who paid and continue to pay artificially inflated prices that inured to the defendants' benefit.

444. It would be wrong and inequitable, under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia—except for Delaware, Georgia, Indiana, Kentucky, Louisiana, New Jersey, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Washington, and Wyoming—for defendants to be permitted to retain any of the overcharges that the plaintiff and members of the class paid for Xyrem that were derived from the defendants' unlawful practices described herein.

445. The defendants are aware of and appreciate the benefits that the plaintiff and members of the class have bestowed upon them.

446. The defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of the plaintiff and class members.

447. The plaintiff and members of the class are entitled to the amount of the defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which the plaintiff and members of the class may make claims on a pro rata basis.

COUNT 14 – FOR INJUNCTIVE RELIEF FOR VIOLATIONS OF 15 U.S.C. §§ 1, 2
(AGAINST ALL DEFENDANTS)

448. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

449. As set forth in Count 1, 2, 3, 4, 5 and 11, Defendants have violated Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

450. The plaintiff requests that the Court granted injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26 as may be necessary and appropriate to restore competition in the market for Xyrem.

XII. DEMAND FOR JUDGMENT

451. WHEREFORE, the plaintiff, on behalf of itself and the proposed class, respectfully demand that this Court:

a) Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and appoint the plaintiff as the named representative of the class;

b) Award the plaintiff and the class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

c) Enter joint and several judgments against the defendants and in favor of the plaintiff and the class;

d) Permanently enjoin defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future;

e) Grant the plaintiff and the class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy the defendants' unjust enrichment;

f) Award the plaintiff and the class their costs of suit, including reasonable attorneys' fees, as provided by law; and

g) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

452. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the plaintiff, on behalf of itself and the proposed class, demand a trial by jury on all issues so triable.

Dated: June 17, 2020

Respectfully submitted,

/s/ Daniel J. Kurowski

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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that on June 17, 2020, a true and correct copy of the foregoing was filed electronically via CM/ECF and is available for viewing and/or downloading from the CM/ECF system and/or Pacer.

/s/ Daniel J. Kurowski
Daniel J. Kurowski